FOOD ADDITIVES

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-FIFTH CONGRESS

ON

BILLS TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO CHEMICAL ADDITIVES IN FOOD

JULY 15, 16, 17, 18, 19, 22, 23, 24, AUGUST 6, 7, 1957, AND APRIL 15, 1958

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FOOD ADDITIVES

MONDAY, JULY 15, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE
OF THE COMMITTEE ON INTERSTATE
AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to call, at 10:15 a. m., in room 1334, New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. This morning the Subcommittee on Health and Science is beginning hearings on a number of bills designed to amend the Federal Food, Drug and Cosmetic Act with regard to chemical additives in food.

Not counting 2 bills which have been superseded by later bills, the subcommittee has pending before it 8 bills on this subject, and at this point the 8 bills, and the departmental reports which I have here, will be made a part of the record.

(The bills and departmental reports are as follows:)

[H. R. 366, 85th Cong., 1st sess.]

A BILL To amend the Federal Food, Drug and Cosmetic Act for the protection of the public health, by prohibiting new food additives which have not been adequately pretested to establish their safe use under the conditions of their intended use

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 201 of the Federal Food, Drug and Cosmetic Act is amended by adding at the end thereof the following new paragraphs (s), (t), and (u):

"(s) The term 'new food additive' means any substance used or intended to be used for any purpose in the manufacture, packing, processing, preparation, or other fabrication of any food, or in the packaging, transporting, or holding of it, which (1) thus becomes or could reasonably be expected to become a component of such food and (2) is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of food, to be safe for use under the conditions of such use or intended use. The term does not include a pesticide chemical in or on a raw agricultural commodity; or, with respect to a particular food or class of foods, any substance to the extent to which, its use for general consumption in the United States in or on such food or class of foods is authorized or approved by the Food and Drug Administration or the Meat Inspection Branch of the United States Department of Agriculture, or any substance to the extent to which its use in or on a food is approved by or under this Act. Each new food additive shall be deemed a food, for the purposes of this Act.

"(t) The term 'safe for use' when used with reference to a new food additive shall mean that it is reasonably probable that such new food additive can be used under the conditions of its intended use without rendering the food in or on which it is used injurious to health.

"(u) The term 'conditions of its intended use' when used with reference to a new food additive includes, but shall not be limited to, specifications as to the particular food or class of foods in or on which said additive is intended to be

used, the quantity intended to be used in or on such food, and the manner in which said additive is intended to be added to or used in or on each such food."

SEC. 2. Paragraph (j) of section 301 of the Federal Food, Drug and Cosmetic Act is amended to read as follows:

"(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, or 704 concerning any method or process which as a trade secret is entitled to protection."

SEC. 3. Section 301 of the Federal Food, Drug and Cosmetic Act is further amended by adding at the end thereof the following new paragraph:

"(o) A violation of section 409 (f)."

SEC. 4. Clauses (1) and (2) of section 402 (a) of the Federal Food, Drug and Cosmetic Act are amended to read as follows:

"(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health, except a new food additive which has been found safe for use under the conditions of its intended use within the meaning of section 409; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such foods does not ordinarily render it injurious to health; or

"(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity, or a new food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is or if it bears or contains a new food additive which is unsafe within the meaning of section 409."

SEC. 5. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new section:

NEW FOOD ADDITIVES

"SEC. 409. (a) Any new food additive shall be deemed unsafe for the application of clause (2) (C) of section 402 (a) unless (1) such additive has been adequately pretested and thereby shown safe for use under the conditions of its intended use; (2) the pretesting data on such additive have been fully submitted to the Secretary, in accordance with this section; and (3) the Secretary has had an opportunity to evaluate said data, as provided by this section.

"(b) The pretesting data on a new food additive submitted to the Secretary shall include, in addition to any explanatory and supporting memoranda—

"(1) the name, and all pertinent information concerning the new food additive, including where available its chemical identity and composition;

"(2) the conditions of the intended use of such additive, including directions, recommendations, and suggestions for the use of such additive;

"(3) a complete description of—

"(A) the methods and controls used in testing the quality and identity of such additive, and

"(B) the methods available for determining the identity and quantity of such additive (including any known reaction products) in or on food;

"(4) a report of the pretesting investigations made to determine whether such additive is safe for use under the conditions of its intended use; and

"(5) any samples of such additive and its component articles requested by the Secretary.

"(c) The Secretary shall promptly evaluate the pretesting data submitted by any person on a new food additive, together with any other available pertinent data, to determine whether in his opinion such additive has been adequately pretested and thereby shown safe for use under the conditions of its intended use; and in doing so the Secretary may consider relevant health factors. The evaluation shall be completed within a period not exceeding ninety days, unless it is extended by mutual agreement of the parties; and during this period such person may consult with the Secretary and submit additional pertinent data and memorandums.

"(d) When the evaluation has been completed the Secretary shall forthwith notify by registered mail the person submitting said pretesting data on a new food additive, whether, in his opinion so reached, such additive has been ade-

quately pretested and thereby shown safe for use under the conditions of its intended use. In notifying the said person of his opinion, the Secretary shall fully state the reasons for his opinion and shall make available to said person such information additional to that supplied by said person which the Secretary has used as a basis for his opinion. In the event the Secretary shall fail to issue an opinion within the time herein prescribed, the Secretary shall be deemed to have issued an opinion that said new food additive has not been adequately pretested and thereby shown safe for use under the conditions of its intended use. The Secretary may thereafter modify or withdraw his opinion whenever he shall deem that newly discovered facts require this action, and shall give notice thereof to all interested parties.

"(e) After an opinion has been issued or deemed to have been issued by the Secretary pursuant to subsection (d), either the Secretary or the person submitting said pretesting data on such new food additive shall have the right to institute an action under the Declaratory Judgments Act (28 U. S. C. 2201) to secure a declaration whether or not such new food additive has been adequately pretested and thereby shown safe for use under the conditions of its intended use, and the trial of such action shall be given precedence and otherwise expedited. This subsection shall not be construed to preclude the institution of any other enforcement proceeding authorized by this Act with respect to such additive or a food bearing or containing it."

"(f) No person who has received an initial notice or opinion by the Secretary, pursuant to subsection (d), which advises that a new food additive has not been adequately pretested and thereby shown safe for use under the conditions of its intended use, shall thereafter introduce or deliver for introduction into interstate commerce such additive or a food bearing or containing it (1) without prior notice to the Secretary given by registered mail at least sixty days before the first proposed shipment, disclosing the identity of said additive, the conditions of its intended use, the date of the proposed shipment and the identity of the proposed consignee, or (2) in the event an action for declaratory judgment is instituted pursuant to subsection (e) and notice given to defendant, until a judgment in such action has become final, declaring that said new food additive has been adequately pretested and thereby shown safe for use under the conditions of its intended use.

"(g) The Secretary shall promulgate regulations to exempt from this section any new food additive and any food bearing or containing such additive when in his opinion such exemption is consistent with the protection of public health. The new food additives and foods thus exempted shall include, but shall not be limited to, new food additives and food intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of food.

"(h) At least six months prior to the effective date of this Act the Secretary shall issue a list of substances which are in his opinion generally recognized to be safe for use in or on the foods or classes of foods specified in said list, in the quantities and under the conditions of use specified in said list, and he may from time to time thereafter supplement said list by the addition of other substances and specifications as to the quantities and conditions of use. The Secretary shall promptly publish said list and each supplement thereto in the Federal Register. The Secretary may from time to time, on at least sixty days' prior notice published in the Federal Register, remove any such substance from said list or modify the quantities or conditions of use so specified. The inclusion of a substance in said list, unless and until it is so removed, shall be conclusive evidence that said substance is generally recognized among the experts described in subsection (s) of section 201 to be safe for use in the quantities, and under the conditions of use in or on the foods or classes of foods specified in said list. The omission or removal of a substance from said list shall not create any presumption that said substance is not generally recognized by the experts described in subsection (s) of section 201 to be safe for use in or on certain foods or classes of foods in certain quantities and under certain conditions of use."

SEC. 6. There are hereby authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purposes and administration of this Act.

SEC. 7. This Act shall take effect one year after the date of its enactment.

[H. R. 6747, 85th Cong., 1st sess.]

A BILL To protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of chemical additives which have not been adequately tested to establish their safety

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Chemical Additives Amendment of 1957".

SEC. 2. Section 201, as amended, of the Federal Food, Drug and Cosmetic Act is further amended by adding at the end of such section the following new paragraph:

"(s) (1) The term 'chemical additive' means, except as otherwise provided in subparagraph (2), any substance the intended use of which results or may result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended to preserve or alter food or for any other purpose in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any radioactive material intended for any such use or as a source for the irradiation of food), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaulate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use.

"(2) Such term does not include (A) a pesticide chemical in or on a raw agricultural commodity, or a pesticide chemical when intended solely for use in the production, storage, or transportation of any raw agricultural commodity; or (B) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act or to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following)."

SEC. 3. Section 201 (f) of such Act is amended to read as follows:

"(f) The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, (3) articles used for components of any such article, and (4) chemical additives."

SEC. 4. (a) Clause (2) of section 402 (a), as amended, of such Act is further amended to read as follows:

"(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a chemical additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408, or (C) if it is, or it bears or contains, any chemical additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the exent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity."

(b) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

SEC. 5. Chapter IV of such Act is amended by adding at the end thereof the following new section:

"CHEMICAL ADDITIVES

"UNSAFE CHEMICAL ADDITIVES

"SEC. 409. (a) A chemical additive shall, with respect to any particular use or intended use of such additive, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) the use or intended use of such additive conforms to the terms of an exemption which is in effect pursuant to subsection (j) of this section; or

"(2) there is in effect, and the use or intended use of such additive is in conformity with, a regulation issued under this section announcing the conditions (including any directions or other labeling or packaging requirements contained in such regulation) under which such additive may be safely used.

While such a regulation relating to a chemical additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) or (2) (C) of section 402 (a).

"PETITION TO ESTABLISH SAFETY

"(b) (1) Any interested person may, with respect to any intended use or uses of a chemical additive, file with the Secretary a petition proposing the issuance of a regulation announcing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to setting forth the regulation proposed by the petitioner and stating reasonable grounds in support of the petition, contain or be accompanied by—

"(A) the name and all pertinent information concerning such chemical additive, including where available its chemical identity and composition;

"(B) (i) a statement of the conditions of the proposed use or uses of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling; and (ii) all relevant data bearing on the functional value of such additive;

"(C) a full description of the methods used in, and the facilities and controls used for, the production of such additive;

"(D) a description of practicable methods for quantitative determination of such additive, and its breakdown or reaction products, in or on food referred to in the petition; and

"(E) full reports of investigations made with respect to the toxicity or other potentiality for harm of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish samples of the chemical additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

"(4) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

"ACTION ON THE PETITION

"(c) (1) As soon as practicable after the filing of the petition, and in no event later than the expiration of the applicable period specified in paragraph (2) of this subsection, the Secretary shall, in the absence of a prior referral or request for referral to an advisory committee made pursuant to this section—

"(A) by order established a regulation (whether or not in accord with that proposed by the petitioner) announcing, with respect to one or more proposed uses of the chemical additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use or uses), and shall notify the petitioner of such order; or

"(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

"2. The order required by paragraph (1) (A) or (B) of this paragraph shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"(3) No such regulation shall issue unless the scientific data submitted or otherwise before the Secretary establish that the proposed use of the chemical additive, under the conditions of use to be specified in the regulation, will be

without hazard to the health of man or other animals consuming any food which is or may, directly or indirectly, be affected by such use, including any food that is yielded by or derived from an animal or plant into which a chemical additive has been introduced by feeding or otherwise, and that such proposed use has functional value; except that the Secretary shall not take functional value into account if he finds that such additive is not a poisonous or deleterious substance.

"(4) In determining, for the purposes of this section, whether a proposed use of a chemical additive is safe, the Secretary shall consider among other relevant factors—

"(A) the probable consumption of the additive and of any food in or on which it is intended to be used as a component;

"(B) the cumulative effect of such additive in the diet of man or other animals concerned, taking into account any chemically or pharmacologically related substance or substances in such diet where relevant because of their use in or on foods; and

"(C) appropriate safety factors for transposing animal experimentation data to practical use in appraising the hazard to man or to other animals expected to consume food that will or may be affected by such chemical additive.

"REGULATION ISSUED ON SECRETARY'S INITIATIVE OR UPON REQUEST

"(d) The Secretary may, at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation announcing, with respect to any particular use or uses of a chemical additive, the conditions under which such additive may be safely used. After the expiration of thirty days after publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal, unless within such thirty-day period a person who is entitled to file a petition under subsection (b) with respect to such additive requests that the proposal, or any question of fact raised thereby, be referred to an advisory committee appointed pursuant to this section.

"REFERENCE TO ADVISORY COMMITTEE

"(e) (1) Within the applicable time limit specified in subsection (c) for action by the Secretary upon a petition but in no event more than thirty days after publication of an order issued pursuant to such subsection, or within thirty days after publication of a proposal for issuance of a regulation pursuant to subsection (d), the petitioner (or, in the case of a proposal under subsection (d), any person entitled to file a petition with respect to the additive involved) may request that such petition or order thereon, or such proposal, or any question of fact raised by such petition, order, or proposal, be referred to an advisory committee. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee of competent experts in accordance with and subject to the provisions of section 408 (g) and shall refer such petition, order, or proposal, or such question of fact, as the case may be, to such committee and furnish it with all the data before him: *Provided*, That the requirement of representation from land-grant colleges on the committee shall not apply and that in the event of the inability or refusal of the National Academy of Sciences to act the Secretary shall select the members of the committee. A person who has filed a petition or who has requested the referral of a proposal to an advisory committee, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it.

"(2) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall confirm or modify any order theretofore issued or, if no such order has been issued, shall establish a regulation announcing, with respect to any particular use or uses

of the chemical additive involved, the conditions under which such additive may be safely used or refuse to establish a regulation.

"(3) The Secretary may by regulation condition referrals to advisory committees pursuant to this subsection upon the payment, by the person requesting the referral, of fees to defray the costs arising by reason of such referrals. Such regulations may provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection. Such fees, including advance deposits to cover such fees, shall be available, until expended, for paying (directly or by way of reimbursement of the applicable appropriation) the expenses of advisory committees under this subsection and other expenses arising by reason of referrals to such committees, and for refunds pursuant to this paragraph.

"PUBLICATION AND EFFECTIVE DATE OF ORDERS

"(f) Any order, including any regulation established by such order, issued under subsection (c), (d), or (e) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if after issuance of such order the petition or any question of fact raised thereby is referred to an advisory committee pursuant to subsection (e) or if a hearing is sought with respect to such order pursuant to subsection (g).

"OBJECTIONS AND PUBLIC HEARING

"(g) Within thirty days after publication, any person adversely affected by an order made pursuant to subsection (c), (d), or (e) of this section may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections: *Provided*, That if, after issuance of an order under subsection (c), the right of referral to an advisory committee is invoked, only the order thereafter issued pursuant to subsection (e) after receipt of the advisory committee's report shall be subject to such objections and public hearing. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing if relevant and material, subject to the provisions of section 7 (c) of the Administrative Procedure Act (5 U. S. C., sec. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and shall by published order either confirm or modify the order to which objections have been filed. Such new order shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"JUDICIAL REVIEW

"(h) In a case of actual controversy as to the validity of any order issued under subsection (g), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review thereof in accordance with, and subject to, the applicable provisions of section 408 (1).

"AMENDMENT OR REPEAL OF REGULATIONS

"(i) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this

section for the promulgation of such regulations, including the appointment of advisory committees and the procedure for referring petitions or proposals to such committees.

"EXEMPTIONS FOR INVESTIGATIONAL OR OTHER USE

"(j) The Secretary (1) shall promulgate regulations providing for exempting from the requirements of this section any chemical additive, and any food bearing or containing such additive, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such additive, and (2) may by regulation exempt any other chemical additive, or any food bearing or containing it, or both, when in his opinion such exemption is consistent with the public health."

SEC. 6. Section 301 (j) of such Act is amended by inserting "409" after "404,".

SEC. 7. (a) Except as otherwise provided in this section this Act shall take effect on the one hundred and eightieth day (hereinafter referred to as the effective date of this Act) after the date of its enactment.

(b) Any interested person desiring to do so may at any time, after the date of enactment and prior to the effective date of this Act, file a petition as provided in subsection (b) of section 409 of the Federal Food, Drug and Cosmetic Act, as enacted by section 5 of this Act, in which event the provisions of such section 409, and of section 201 (s) and section 301 (j) of such Act as amended by this Act, shall become effective immediately as applied to such petition and to proceedings thereon; but nothing in this subsection shall be construed to accelerate the effective date of the remaining provisions of this Act.

(c) Where a chemical additive was in use for one or more purposes immediately prior to the date of enactment of this Act, the amendments to sections 402 (a) and 406 (a) of the Federal Food, Drug and Cosmetic Act made by section 4 of this Act shall not, as applied to such preexisting use or uses of such additive, become effective until—

(1) the final establishment of a regulation or exemption relating to such use or uses pursuant to section 409 of such Act or the final denial of a petition for such regulation or exemption (without, in either case, further opportunity for referral to an advisory committee, for an administrative hearing, or for judicial review); or

(2), if earlier, the expiration of either (A) the one-year period beginning on the date following the effective date of this Act, or (B) such additional period (not extending beyond two years after the effective date of this Act) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such additional period.

SEC. 8. There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, such sums as may be necessary for the administration of this Act.

SEC. 9. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following).

[H. R. 7700, 85th Cong., 1st sess.]

A BILL To protect the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 201 of the Federal Food, Drug and Cosmetic Act is amended by the addition of the following paragraph:

"(s) The term 'chemical additive' means any substance (including products resulting from changes in such substance after use) which (1) is intended for use (A) as a food, or (B) to preserve or alter any food or any characteristic of any food; or (C) for any other purposes in producing, processing, packing, transporting, wrapping, or holding food if such use is likely to result in the contamination of food, but shall not include pesticide chemicals used in the production, storage, or transportation of raw agricultural commodities, as defined in section 201 (q) of this Act; and (2) is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of chemical additives,

as having been adequately tested to show that it is not poisonous or deleterious, or is a poisonous or deleterious substance which is not generally recognized among such experts as having been adequately tested to show that it is safe for its intended use."

SEC. 2. Section 301 of the Federal, Drug and Cosmetic Act is amended by changing "404 or 505" in subsection (d) to "404, 409, or 505"; and "404, 505, 506, 507, or 704" in subsection (j) to "404, 409, 505, 506, 507, or 704".

SEC. 3. Section 304 of such Act is amended by changing "404 or 505" in subsections (a) and (d) to "404, 409, or 505".

SEC. 4. Section 402 (a) of such Act is amended by changing the period at the end to a semicolon and adding: "or (7) if it is, or bears or contains, a chemical additive, unless the use of such chemical additive has been approved pursuant to section 409."

SEC. 5. The following section shall be added to chapter IV of such Act:

"CHEMICAL ADDITIVES

"SEC. 409. (a) No person shall introduce or deliver for introduction into interstate commerce any chemical additive, unless the use of such chemical additive has been approved pursuant to this section.

"(b) Any person may file with the Secretary an application for the issuance of an order approving the use of a chemical additive. There shall be submitted to the Secretary with the application (1) a statement of the intended use of the chemical additive and demonstrating that such employment of the chemical additive will serve a purpose which will be useful to the consuming public; (2) reports of investigations which have been made to determine the acute and chronic toxicity and other potentiality for harm of the chemical additive; (3) a statement of the composition of the chemical additive; (4) a description of methods of analysis for the quantitative determination of the chemical additive, and its reduction products, in or on food; (5) such samples of the chemical additive as the Secretary may require; (6) all directions, recommendations, and suggestions proposed for the use of the chemical additive; and (7) if the chemical additive is a poisonous or deleterious substance, reports of investigations which have been made to show the quantities of the chemical additive remaining in or on the food and that it is required for its intended use.

"(c) The Secretary shall issue an order approving the application within ninety days after the filing of the application if the Secretary finds that the reports submitted to him pursuant to subsection (b) demonstrate (1) that the chemical additive is not a poisonous or deleterious substance or if it is that it is safe and required for its intended use, and (2) that the intended use of the chemical additive will serve a purpose which will be useful to the consuming public; otherwise, except as provided in subsection (d), the Secretary shall issue an order within said ninety days refusing to approve the application.

"(d) Within said ninety-day period specified in subsection (c), the Secretary, when he deems such action advisable or upon notification from the applicant, shall submit the application and other data before him to an advisory committee to be appointed pursuant to subsection (f). Within sixty days after such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee, after independent study of the data submitted to it by the Secretary, shall certify to him a report and recommendations on the proposal in the application, together with all underlying data and a statement of the reasons for the recommendations. Within thirty days after such certification, the Secretary, after giving due consideration to all the material, including such report and recommendations, then before him, shall issue an order approving the application if he finds that the chemical additive is not a poisonous or deleterious substance or if it is that it is safe and required for its intended use, and that its intended use will serve a purpose which will be useful to the consuming public; otherwise the Secretary shall issue an order within said thirty days refusing to approve the application. In determining whether a chemical additive is safe under subsection (c) or (d), the Secretary shall take into account the other ways in which the consumer may be affected by the same substance or other substances.

"(e) Within thirty days after the issuance of an order under subsection (c) or (d), any person adversely affected may file objections thereto with the Secretary specifying the reasons he deems the order objectionable and requesting a public hearing upon such objections. After furnishing due notice, the Secretary shall thereupon hold a public hearing for the purpose of receiving evidence

relevant and material to the issues raised by such objections. Any report, recommendations, underlying data and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing. The advisory committee shall designate one of its members to appear and testify at any such hearing with respect to its report and recommendations upon request of the officer conducting the hearing or any person adversely affected: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and issue an order. Such order shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the order is based. No such order shall take effect prior to the ninetieth day of its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event he shall specify in the order his findings as to such conditions.

"(f) Whenever an application is referred to an advisory committee, the Secretary shall appoint a committee of competent experts to review the application and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts qualified in the subject matter of the application and of adequately diversified professional background selected by the National Academy of Sciences: *Provided*, That in the event of disability or refusal of the National Academy of Sciences to act, the Secretary shall select such a committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance.

"(g) Any person adversely affected, and representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (f) in connection with the application.

"(h) Orders issued under this section, and orders amending or repealing such orders, may be appealed by any person adversely affected in accordance with the provisions of section 505 (h): *Provided*, That the findings of the Secretary shall be sustained if supported by substantial evidence when considered on the record as a whole.

"(i) The Secretary shall promulgate regulations establishing the procedure by which orders issued under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations, including the appointment of advisory committees and the procedure for referring applications to such committees.

"(j) The Secretary shall promulgate regulations exempting from the operation of this section chemical additives intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such chemical additives."

SEC. 6. The Secretary of Health, Education, and Welfare, by regulation, shall require the payment of such fees for the performance of the Secretary's functions under this statute as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for such function.

SEC. 7. This statute shall take effect six months after the date of its enactment.

[H. R. 7798, 85th Cong., 1st sess.]

A BILL To protect the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 201 of the Federal Food, Drug and Cosmetic Act is amended by the addition of the following paragraph:

"(s) The term 'chemical additive" means any substance (including products resulting from changes in such substance after use) which (1) is intended for use (A) as a food, or (B) to preserve or alter any food or any character-

istic of any food, including any radioactive material intended for any such use; or (C) for any other purpose in producing, processing, packing, transporting, wrapping, or holding food if such use is likely to result in the contamination of food, including any radioactive material intended for any such use, but shall not include pesticide chemicals used in the production, storage, or transportation of raw agricultural commodities, as defined in section 201 (q) of this Act; and (2) is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of chemical additives, as having been adequately tested to show that it is not poisonous or deleterious, or is a poisonous or deleterious substance which is not generally recognized among such experts as having been adequately tested to show that it is safe for its intended use."

SEC. 2. Section 301 of the Federal Food, Drug and Cosmetic Act is amended by changing "404 or 505" in subsection (d) to "404, 409, or 505"; and "404, 505, 506, 507, or 704" in subsection (j) to "404, 409, 505, 506, 507, or 704."

SEC. 3. Section 304 of such Act is amended by changing "404 or 505" in subsections (a) and (d) to "404, 409, or 505".

SEC. 4. Section 402 (a) of such Act is amended by changing the period at the end to a semicolon and adding: "or (7) if it is, or bears or contains, a chemical additive, unless the use of such chemical additive has been approved pursuant to section 409."

SEC. 5. The following section shall be added to chapter IV of such Act:

"CHEMICAL ADDITIVES

"SEC. 409. (a) No person shall introduce or deliver for introduction into interstate commerce any chemical additive, unless the use of such chemical additive has been approved pursuant to this section.

"(b) Any person may file with the Secretary an application for the issuance of an order approving the use of a chemical additive. There shall be submitted to the Secretary with the application (1) a statement of the intended use of the chemical additive and demonstrating that such employment of the chemical additive will serve a purpose which will be useful to the consuming public; (2) reports of investigations which have been made to determine the acute and chronic toxicity, carcinogenicity, and other potentiality for harm of the chemical additive; (3) a statement of the composition of the chemical additive; (4) a description of methods of analysis for the quantitative determination of the chemical additive, and its reduction products, in or on food; (5) such samples of the chemical additive as the Secretary may require; (6) all directions, recommendations, and suggestions proposed for the use of the chemical additive; and (7) if the chemical additive is a poisonous or deleterious substance, reports of investigations which have been made to show the quantities of the chemical additive remaining in or on the food and that it is required for its intended use.

"(c) The Secretary shall issue an order approving the application within ninety days after the filing of the application if the Secretary finds that the reports submitted to him pursuant to subsection (b) demonstrate (1) that the chemical additive is not a poisonous or deleterious substance or if it is that it is safe and required for its intended use, and (2) that the intended use of the chemical additive will serve a purpose which will be useful to the consuming public; otherwise, except as provided in subsection (d), the Secretary shall issue an order within said ninety days refusing to approve the application.

"(d) Within said ninety-day period specified in subsection (c), the Secretary, when he deems such action advisable or upon notification from the applicant, shall submit the application and other data before him to an advisory committee to be appointed pursuant to subsection (f). Within sixty days after such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee, after independent study of the data submitted to it by the Secretary, shall certify to him a report and recommendations on the proposal in the application, together with all underlying data and a statement of the reasons for the recommendations. Within thirty days after such certification, the Secretary, after giving due consideration to all the material, including such report and recommendations, then before him, shall issue an order approving the application if he finds that the chemical additive is not a poisonous or deleterious substance or if it is that it is safe and required for its intended use, and that its intended use will serve a purpose which will

be useful to the consuming public; otherwise the Secretary shall issue an order within said thirty days refusing to approve the application. In determining whether a chemical additive is safe under subsection (c) or (d), the Secretary shall take into account the other ways in which the consumer may be affected by the same substance or other substances, including any hazard to the health of the consumer from food which is yielded by, or derived from, any animal or plant into which such chemical additive has been introduced by feeding or otherwise. The Secretary shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals.

"(e) Within thirty days after the issuance of an order under subsection (c) or (d), any person adversely affected may file objections thereto with the Secretary specifying the reasons he deems the order objectionable and requesting a public hearing upon such objections. After furnishing due notice, the Secretary shall thereupon hold a public hearing for the purpose of receiving evidence relevant any material to the issues raised by such objections. Any report, recommendations, underlying data and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing. The advisory committee shall designate one of its members to appear and testify at any such hearing with respect to its report and recommendations upon request of the officer conducting the hearing or any person adversely affected: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearings, the Secretary shall act upon such objections and issue an order. Such order shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the order is based. No such order shall take effect prior to the ninetieth day of its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event he shall specify in the order his findings as to such conditions.

"(f) Whenever an application is referred to an advisory committee, the Secretary shall appoint a committee of competent experts to review the application and to make a report and recommendations, thereon. Each such advisory committee shall be composed of experts qualified in the subject matter of the application and of adequately diversified professional background selected by the National Academy of Sciences: *Provided*, That in the event of disability or refusal of the National Academy of Sciences to act, the Secretary shall selected such a committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance.

"(g) Any person adversely affected, and representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (f) in connection with the application.

"(h) Orders issued under this section, and orders amending or repealing such orders, may be appealed by any person adversely affected in accordance with the provisions of section 505 (h): *Provided*, That the findings of the Secretary shall be sustained if supported by substantial evidence when considered on the record as a whole.

"(i) The Secretary shall promulgate regulations establishing the procedure by which orders issued under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations, including the appointment of advisory committees and the procedure for referring applications to such committees.

"(j) The Secretary shall promulgate regulations exempting from the operation of this section chemical additives intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such chemical additives."

SEC. 6. The Secretary of Health, Education, and Welfare, by regulation, shall require the payment of such fees for the performance of the Secretary's functions under this statue as will in the aggregate, in the judgment of the Secretary, be

sufficient over a reasonable term to provide, equip, and maintain an adequate service for such function.

SEC. 7. This statute shall take effect six months after the date of its enactment.

(NOTE.—H. R. 7938, introduced by Mrs. Sullivan, of Missouri, is identical with H. R. 7798.)

[H. R. 8112, 85th Cong., 1st sess.]

A BILL To protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of food additives which have not been adequately tested to establish their safety

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Amendment of 1957".

SEC. 2. Section 201, as amended, of the Federal Food, Drug and Cosmetic Act is further amended by adding at the end of such section the following new paragraph:

"(s) (1) The term 'food additive' means, except as otherwise provided in subparagraph (2), any ingredient intentionally added to food and becoming a component part of food for the purpose of imparting a desired quality to the food, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use.

"(2) Such term does not include (A) a pesticide in or on a raw agricultural commodity, or a pesticide when intended solely for use in the production, storage, or transportation of any raw agricultural commodity; or (B) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act or to the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following), or (C) an incidental food additive: *Provided*, That no sanction or approval heretofore granted formally or informally in accordance with this Act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following) shall be withdrawn without proper notice and hearing in accordance with the applicable provisions of the Administrative Procedure Act (5 U. S. C. 1001, and the following:

"(t) (1) The term 'incidental food additive' means any substance intended for use in manufacturing, packing, processing, preparing, treating, packaging, or transporting food which foreseeably results, in the course of good manufacturing practice, in its getting into the food; including any radioactive material intended for such use or as a source for the irradiation of food.

"(t) (2) Such term does not include substances described in section 201 (s) (2) (A) and section 201 (s) (2) (B)."

SEC. 3. (a) Clause (2) of section 402 (a), as amended, of such Act is further amended to read as follows:

"(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide in or on a raw agricultural commodity and except a food additive, or an incidental additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide which is unsafe within the meaning of section 408, or (C) if it bears or contains any intentional food additive which is unsafe within the meaning of section 409, or (D) if it bears or contains any incidental food additive which is unsafe within the meaning of section 410: *Provided*, That where a pesticide has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating, or milling, the residue of such pesticide remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity."

(b) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

SEC. 4. Chapter IV of such Act is amended by adding at the end thereof the following new section:

"FOOD ADDITIVES

"UNSAFE FOOD ADDITIVES

"SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additive, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) the use or intended use of such additive conforms to the terms of an exemption which is in effect pursuant to subsection (j) of this section; or

"(2) there is in effect, and the use or intended use of such additive is in conformity with, a regulation issued under this section announcing the conditions (including any directions or other labeling or packaging requirements contained in such regulations) under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) or (2) (C) of section 402 (a).

"PETITION TO ESTABLISH SAFETY

"(b) (1) Any interested person may, with respect to any intended use or uses of a food additive, file with the Secretary a petition proposing the issuance of a regulation announcing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to setting forth the regulation proposed by the petitioner and stating reasonable grounds in support of the petition, contain or be accompanied by—

"(A) the name and all pertinent information concerning such food additive, including where available its chemical identity and composition;

"(B) (i) a statement of the conditions of the proposed use or uses of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive;

"(C) a full description of the methods used in, and the facilities and controls used for, the testing of quality of such additive;

"(D) a description of practicable methods for quantitative determination of such additive, and, to the extent known, its breakdown or reaction products, in or on food referred to in the petition; and

"(E) full reports of investigations made with respect to the toxicity or other potentiality for harm of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

"(4) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

"ACTION ON THE PETITION

"(c) (1) As soon as practicable after the filing of the petition, and in no event later than the expiration of the applicable period specified in paragraph (2) of this subsection, the Secretary shall, in the absence of a prior referral or request for referral to an advisory committee made pursuant to this section—

"(A) by order established a regulation (whether or not in accord with that proposed by the petitioner) announcing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including specifications as to the particular food or classes of food in or on which such additive may be used and the maximum quantity which may be used or permitted to remain in or on such food), and shall notify the petitioner of such order; or

"(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

"(2) The order required by paragraph (1) (A) or (B) of this paragraph shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one

hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"(3) No such regulation shall issue unless the scientific data submitted or otherwise before the Secretary establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be without reasonable probability of hazard to the health of man or other animals consuming any food which is or may, directly or indirectly, be affected by such use, including any food that is yielded by or derived from an animal or plant into which a food additive has been introduced by feeding or otherwise.

"(4) In determining for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

"(A) the probable consumption of the additive and of any food in or on which it is intended to be used as a component;

"(B) the cumulative effect of such additive in the diet of man or other animals concerned, taking into account any substance or substances in such diet where relevant because of their use in or on foods; and

"(C) appropriate safety factors for transposing animal experimentation data to practical use in appraising the hazard to man or to other animals expected to consume food that will or may be affected by such food additive.

"REGULATION ISSUED ON SECRETARY'S INITIATIVE OR UPON REQUEST

"(d) The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation announcing, with respect to any particular use or uses of a food additive or an incidental additive, the conditions under which such additive may be safely used. After the expiration of thirty days after publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal, unless within such thirty-day period a person who is entitled to file a petition under subsection (b) with respect to such additive requests that the proposal, or any question of fact raised thereby, be referred to an advisory committee appointed pursuant to this section.

"REFERENCE TO ADVISORY COMMITTEE

"(e) (1) Within the applicable time limit specified in subsection (c) for action by the Secretary upon a petition but in no event more than thirty days after publication of an order issued pursuant to such subsection, or within thirty days after publication of a proposal for issuance of a regulation pursuant to subsection (d), the petitioner (or, in the case of a proposal under subsection (d), any person entitled to file a petition with respect to the additive involved) may request that such petition or order thereon, or such proposal, or any question of fact raised by such petition, order, or proposal, be referred to an advisory committee. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee of competent experts in accordance with and subject to the provisions of section 408 (g) and shall refer such petition, order, or proposal, or such question of fact, as the case may be, to such committee and furnish it with all the data before him: *Provided*, That the requirement of representation from land-grant colleges on the committee shall not apply and that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committeee. A person who has filed a petition or who has requested the referral of a proposal to an advisory committee, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it.

"(2) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall confirm or modify any order theretofore issued, or, if no such order has been issued, shall establish a regulation announcing, with respect to any particular use or uses of

the food additive involved, the conditions under which such additive may be safely used or refuse to establish a regulation.

"(3) The Secretary may by regulation condition referrals to advisory committees pursuant to this subsection upon the payment, by the person requesting the referral, of fees to defray the costs arising by reason of such referrals. Such regulations may provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection. Such fees, including advance deposits to cover such fees, shall be available, until expended, for paying (directly or by way of reimbursement of the applicable appropriation) the expenses of advisory committees under this subsection and other expenses arising by reason of referrals to such committees, and for refunds pursuant to this paragraph.

"PUBLICATION AND EFFECTIVE DATE OF ORDERS

"(f) Any order, including any regulation established by such order, issued under subsection (c), (d), or (e) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if after issuance of such order the petition or any question of fact raised thereby is referred to an advisory committee pursuant to subsection (e) or if a hearing is sought with respect to such order pursuant to subsection (g).

"OBJECTIONS AND PUBLIC HEARING

"(g) Within thirty days after publication, any person adversely affected by an order made pursuant to subsection (c), (d), or (e) of this section may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections: *Provided*, That if after issuance of an order under subsection (c), the right of referral to an advisory committee is invoked, only the order thereafter issued pursuant to subsection (e) after receipt of the advisory committee's report shall be subject to such objections and public hearing. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence revelant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing if relevant and material, subject to the provisions of section 7 (c) of the Administrative Procedure Act (5 U. S. C. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and shall by published order either confirm or modify the order to which objections have been filed. Such new order shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"JUDICIAL REVIEW

"(h) In a case of actual controversy as to the validity of any order issued under subsection (g), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review thereof in accordance with, and subject to, the applicable provisions of section 408 (i).

"AMENDMENT OR REPEAL OF REGULATIONS

"(i) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this

section for the promulgation of such regulations, including the appointment of advisory committees and the procedure for referring petitions or proposals to such committees.

"EXEMPTIONS FOR INVESTIGATIONAL OR OTHER USE

"(j) The Secretary (1) shall promulgate regulations providing for exempting from the requirements of this section any food additive, and any food bearing or containing such additives, intended solely for investigational use by experts, qualified by scientific training and experience to investigate the safety of such additive, and (2) may by regulation exempt any other food additive, or any food bearing or containing it, or both, when in his opinion such exemption is consistent with the public health."

SEC. 5. Chapter IV of such Act is further amended by adding after the aforementioned new section 409, the following new section:

"INCIDENTAL FOOD ADDITIVES

"SEC. 410. (a) An incidental food additive shall be deemed to be unsafe for the purposes of the application of clause 2 (D) of section 402 (a) unless an application filed pursuant to subsection (b) is effective with respect to such incidental food additive.

"(b) Any person may file with the Secretary an application with respect to any incidental food additive subject to the provisions of subsection (a). Such application shall consist of a full report of investigations which have been made to show whether or not such incidental food additive migrates into food in a quantity which is toxicologically significant from the standpoint of the protection of public health.

"(c) An application provided for in subsection (1) shall be effective on the ninetieth day after the filing thereof unless, prior to such day, the Secretary issues an order refusing to permit the application to become effective: *Provided, however*, That such order must be supported by a statement of reasonable grounds showing that use of such incidental food additive creates a probable risk of injury to public health.

"(d) In the event that the Secretary issues an order refusing to permit an application to become effective, such incidental food additive shall be deemed to be unsafe under clause (2) (D) of section 402 (a) until such time as (1) the Secretary issues a regulation establishing the safety of the proposed additive under section 409 of this Act, or (2) if the order is set aside upon appeal as hereinafter provided in subsection (e).

"(e) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective in accordance with section 701 (f) of this Act."

SEC. 6. Section 701 (f) (1), as amended, of the Federal Food, Drug and Cosmetic Act is further amended as follows:

"(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), or any order under section 410 of this Act, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the circuit court of appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order."

SEC. 7. Section 301 (j) of such Act is amended by inserting "409, 410" after "404,".

SEC. 8. (a) Except as otherwise provided in this section, this Act will take effect on the one hundred and eightieth day (hereinafter referred to as the effective date of this Act) after the date of its enactment.

(b) Any interested person desiring to do so may at any time, after the date of enactment and prior to the effective date of this Act, file a petition as provided in subsection (b) of section 409 of the Federal Food, Drug and Cosmetic Act, as enacted by section 4 of this Act, or an application as provided in subsection (b) of section 410 of the Federal Food, Drug and Cosmetic Act as enacted by section 5 of this Act, in which event the provisions of such sections 409 and 410, and of sections 201 (s) and (t) and section 301 (j) of such Act as amended by this Act,

shall become effective immediately as applied to such petition and to proceedings thereon; but nothing in this subsection shall be construed to accelerate the effective date of the remaining provisions of this Act.

(c) Where a food additive was in use for one or more purposes immediately prior to the date of enactment of this Act, the amendments to sections 402 (a) and 406 (a) of the Federal Food, Drug and Cosmetic Act made by section 4 of this Act shall not, as applied to such preexisting use or uses of such additive, become effective until—

(1) the final establishment of a regulation or exemption relating to such use or uses pursuant to section 409 or 410 of such Act or the final denial of a petition for such regulation or exemption (without, in either case, further opportunity for referral to an advisory committee, for administrative hearings, or for judicial review); or

(2), if earlier, the expiration of either (A) the one-year period beginning on the date following the effetcive date of this Act, or (B) such additional period (not extending beyond two years after the effective date of this Act) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such additional period.

SEC. 8. There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, such sums as may be necessary for the administration of this Act.

SEC. 9. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following).

[H. R. 8390, 85th Cong., 1st sess.]

A BILL To protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Amendment of 1957".

SEC. 2. Section 201, as amended, of the Federal Food, Drug and Cosmetic Act is further amended by adding at the end of such section the following new paragraph:

"(s) (1) The term 'new food additive' means any substance used or intended to be used for any purpose in the manufacture, packing, processing, preparation, or other fabrication of any food, or in the packaging, transporting, or holding of it, which (A) becomes or could reasonably be expected to become a component of such food or as used to affect the characteristics of such food; and which (B) is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of food, to be safe for use under the conditions of such use or intended use.

"(2) The term 'new food additive' does not include (A) a pesticide chemical in or on a raw agricultural commodity, or a pesticide chemical when intended solely for use in the production, storage, or transportation of any raw agricultural commodity; or (B) any substance used in accordance with a sanction or approval, formal or informal, shown to have been granted prior to the enactment of this paragraph, in the administration of this Act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following)."

SEC. 3. Section 201 (f) of such Act is amended to read as follows:

"(f) The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, (3) articles used for components of any such article, and (4) food additives."

SEC. 4. (a) Clause (2) of section 402 (a), as amended, of such Act is further amended to read as follows:

"(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section

408, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409.

"Subsection (C) of this clause shall not be applicable to any pesticide chemical which has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 where such raw agricultural commodity has been subjected to processing by cooking, canning, freezing, dehydrating, or milling, and the residue of such pesticide chemical remaining in or on such processed food has been reduced to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity."

(b) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

SEC. 5. Chapter IV of such Act is amended by adding at the end thereof the following new section:

FOOD ADDITIVES

UNSAFE FOOD ADDITIVES

"SEC. 409. (a) Any new food additive shall be deemed to be unsafe for the application of clause (2) (C) of section 402 (a), unless (1) such additive has been adequately pretested; (2) is safe for use under the conditions of its intended use; (3) the pretesting data on such additive have been fully submitted to the Secretary, and the Secretary has had an opportunity to evaluate said data in accordance with this section. The Secretary shall hold the data thus submitted in confidence, except where their disclosure is required either to protect the public health or in an enforcement proceeding under this Act.

"(b) The pretesting data on a new food additive submitted to the Secretary shall include, in addition to any explanatory and supporting memoranda—

"(1) the name and all pertinent information about such additive, including, where available, its chemical identity and composition;

"(2) the conditions of the intended use of such additive in the food or foods, including directions, recommendations, and suggestions for the use of such additive, and its proposed labeling;

"(3) a complete description of—

"(A) the methods and controls used in testing such additive, and

"(B) the methods available for determing the identity and quantity of such additive (including any known reaction products) in or on foods;

"(4) a report of the pretesting investigations made to determine whether such additive is safe for use under the conditions of its indended use; and

"(5) any samples of such additive and its component articles which may be requested by the Secretary.

"(c) The Secretary shall promptly evaluate the pretesting data submitted by any person on a new food additive together with any other pertinent data, to determine whether in his opinion such additive has been adequately pretested and, if so adequately pretested, is safe for use under the conditions of its intended use; and in doing so the Secretary may consider all relevant safety factors. The evaluation shall be completed within a period not exceeding one hundred and twenty days, unless it is extended by mutual agreement of the parties; and during this period such person may consult with the Secretary and submit additional pertinent data and memoranda.

"(d) When the evaluation has been completed the Secretary shall forthwith notify by registered mail the person submitting said pretesting data on a new food additive, whether, in his opinion so reached, (1) such additive has been adequately pretested and (2) if so adequately pretested, is safe for use under the conditions of its intended use. In notifying such person of his opinion, the Secretary shall state the reasons for his opinion and shall indicate any information in addition to that supplied by such person, used by the Secretary as a basis for his opinion.

"(e) If the opinion is favorable the Secretary nevertheless may thereafter modify or withdraw it by written notice to such person, whenever in the opinion of the Secretary newly discovered facts require this action to protect the public health.

"(f) No person who has thus received an initial opinion or a notice by the Secretary, pursuant to subsection (d), that a new food additive has not been adequately pretested or is unsafe for use under the conditions of its intended use shall thereafter introduce or deliver for introduction into interstate commerce

such additive or a food bearing or containing it, without prior notice to the Secretary given by registered mail at least ninety days before the proposed first shipment which notice shall specify its identity and the identity of the food in which it is to be used, the quantity, and destination and consignee.

"(g) Whenever the Secretary shall determine that action is necessary to protect the public health, he shall cause an appropriate injunction proceeding to be instituted under section 302 to restrain a violation of section 301 (a) with respect to such additive or a food bearing or containing it; and the final hearing in said proceeding shall be given precedence and otherwise expedite. In said proceeding a temporary restraining order may be issued in accordance with the Federal Rules of Civil Procedure before the United States District Court promulgated under the Act of June 25, 1948 (ch. 646, 62 Stat. 961), as amended (28 U. S. C. 2072). For the purpose of determining whether such temporary restraining order shall issue, the relevant pretesting data submitted by the defendant under this section shall be taken as admissions by him. This subsection, however, shall not be construed to preclude the institution of any other enforcement proceeding authorized by this Act, with respect to such new additive or any food bearing or containing it.

"(h) No person shall be subject to the penalties of section 303 (a) for having received in interstate commerce and used in good faith a new food additive or any food containing it, if he establishes a guaranty, signed by and containing the name and address of the person residing in the United States from whom he received such additive, to the effect that as so used such additive or the food containing it is not adulterated or misbranded within the meaning of this Act."

EXEMPTIONS FOR INVESTIGATIONAL OR OTHER USE

"(i) The Secretary (1) shall promulgate regulations providing for exempting from the requirements of this section any new food additive, or any food bearing or containing such additive, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such additives, and (2) may by regulation exempt any other new food additive, or any food bearing or containing it, or both, when in his opinion such exemption is consistent with the public health."

SEC. 6. There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, such sums as may be necessary for the administration of this Act.

SEC. 7. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following).

(NOTE.—H. R. 8629, introduced by Mr. Wolverton, of New Jersey, is identical with H. R. 8390. H. R. 10404, introduced by Mr. Williams of Mississippi was later considered and appears on p. 532.)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
July 12, 1957.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your request for a report on H. R. 366, a bill to amend the Federal Food, Drug and Comestic Act for the protection of the public health by prohibiting new food additives which have not been adequately pretested to establish their safe use under the conditions of their intended use.

This bill deals with the problem of safety to the consumer arising from the widespread and increasing use of chemicals in modern food-processing technology. It is similar to H. R. 8271 and H. R. 8275 on which, together with other bills, we reported to your committee on February 1, 1956. (The report is reprinted on p. 138 et seq. of the published record of hearings on H. R. 4099 and other bills, held by a subcommittee of your committee on February 1, 2, 3, and 14, 1956.)

We endorse the fundamental objectives of the bill, but, for the reasons stated below, we believe that, unlike this Department's proposal (embodied in H. R. 6747), the bill would not accomplish the goal of affording adequate protection to the consumer from the use of unsafe food additives.

1. As explained in the enclosed memorandum, the definition of "new food additive" in H. R. 366 appears to be incomplete.

2. The safety standard of the bill, i. e., that it must be "reasonably probable" that the additive can be used under the conditions of its intended use without rendering "the food in or on which it is used" injurious to health, is inadequate for two reasons: In the first place, "reasonable probability" of safety does not, in our judgment, afford an adequate margin of safety to allow for the inevitable residual risk that inheres in allowing a poisonous substance to be added to food even in apparently safe amounts. In the second place, to consider only the particular food involved in determining the safety of an additive substance and thus leave out of account the combined effect of that and other substances in the consumer's total diet, would be to go back to a long superseded standard which has proved inadequate. (See the discussion in the enclosed memorandum.)

3. The bill does not require that the proposed use of an additive be shown to be useful or have functional value, even where the additive is an active poison. As explained in the enclosed memorandum, we can see no reason for admitting an additive which is not a clearly harmless substance into the food supply unless some benefit to the producer or consumer is shown to flow from its proposed use.

4. The bill would require the submission of pretesting data, with respect to a chemical additive, to the Secretary, but it would give no effect, except a delaying effect, to an adverse safety evaluation of the Secretary. It would, as a practical matter, force the Secretary to sue for a declaratory judgment to obtain a safety decision in the courts and stop the marketing of an unsafe additive, and of food containing it, if the sponsor gives notice that he intends to market the additive or such food in the face of our adverse evaluation. (Moreover, as the bill is drawn, the requirement to notify us of an intended shipment would apply only to the person submitting the pretesting data, and our adverse evaluation would not legally operate to prevent shipments by others.)

In our judgment, the standard administrative-procedure approach providing for a safety regulation judicially reviewable on the basis of an administrative hearing record, rather than the judicial-trial approach embodied in this bill, is the appropriate one here. This is because, among other things, (*a*) no weight would be attached under the bill to the administrative evaluation of an additive and the courts would be required to exercise a difficult scientific and perhaps policy judgment; and (*b*) the procedure involved would be extremely burdensome and costly for private litigants, the Government, and the courts, and probably would prove unworkable.

These reasons are explained in more detail in our above-mentioned report on H. R. 8271 and H. R. 8275, 84th Congress, bills which are very similar to the present bill in this respect. (See pp. 143, 144, of the hearings.) This feature of the earlier bills was also adversely commented on by the Department of Justice in its report on those bills (printed on p. 25 of the hearings) and in testimony on behalf of the Judicial Conference of the United States by Chief Judge John Biggs, Jr., of the third judicial circuit (on pp. 48–56 of the hearings).

It is significant that your committee considered and rejected the judicial-trial approach in its study of bills which preceded the passage of legislation to control pesticide-chemical residues on raw agricultural commodities. That legislation affords essentially the same type of protection with respect to pesticide chemicals as we believe is necessary for other food additives.

There are a number of lesser items in connection with the present bill that we are not discussing at this time because of our views on the fundamental questions raised above.

For the reasons stated, we recommend against enactment of this bill.

As above mentioned, we have submitted to the Congress a legislative proposal, introduced by you as H. R. 6747 (Chemical Additives Amendment of 1957), "to prohibit the use in food of chemical additives which have not been adequately tested to establish their safety." H. R. 6747 is not subject to the above-mentioned objections, and we urge its enactment in lieu of H. R. 366.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

H. R. 366—MEMORANDUM ON DEFINITION OF "NEW FOOD ADDITIVE," SAFETY STANDARD, AND LACK OF FUNCTIONAL VALUE REQUIREMENT

1. The definition of "new food additive" in the bill (sec. 201 (s)) is limited. It is doubtful that, as drawn, it would cover new substances produced in food by the use of a food additive if they are not identical with the food additive

itself. It fails, moreover, to provide that the Secretary shall consider the safety of food products, such as meat, milk, or eggs, derived from animals fed new food additives or feed treated with them. Further, the proposed definition of a "new food additive" in section 201 (s) of the bill does not indicate clearly that it includes radioactive material or sources intended for use in, or for irradiation of, food.

2. The proposed section 201 (t) defines the expression "safe for use," when used with reference to a new food additive, as meaning "that it is reasonably probable that such new food additive can be used under the conditions of its intended use without rendering the food in or on which it is used injurious to health." We think that, for two reasons, this is not an acceptable safety standard.

In the first place, bearing in mind that this proposed legislation is intended to permit the addition of active poisons, as well as other food additives, to the food supply of the Nation, we do not believe that the public health would be adequately protected by permitting the addition of an additive to food merely on the basis of a showing that it is "reasonably probable" that it will not be injurious. On the contrary, we think that chemical additives not generally recognized by experts as safe should be permitted in food only upon a showing, based on sound scientific data, that the use of the additive in or in connection with the production of food will be without hazard to the health of man or lower animals for whom the food is intended.

In the second place, the proposed section 201 (t) would require only a showing that a new food additive—even an active poison—can be used under the conditions of its intended use without rendering "the food in or on which it is used injurious to health." This provision would result in a serious retrogression in the protection available to the consumer under the Federal food statutes. It would require the Government to consider each food alone, and if it did not contain sufficient added poison to render it "injurious to health," the Government would be powerless to act. This was the method of control tried under the original Food and Drug Act of 1906. It became apparent under the 1906 statute that the total intake of poison by a consumer could not be controlled on a single-product basis; for example, if each of 3 items of food should contain one-third of the amount of a poison that would make it injurious, then each would have been legal under the 1906 law, but the consumer who was unfortunate enough to eat these 3 items together could be harmed. Hence, section 406 (a) of the present act (which the bill would make inapplicable to new food additives) requires us, in establishing a tolerance for a necessary poisonous additive, to take into account "the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances." It is important that new legislation to control food additives require the Government, in evaluating the safety of a proposed use of a new additive, to consider the cumulative effect thereof in the light of the total lifetime diet of man (or of lower animals in the case of animal feed), rather than limit its consideration to the safety of a single food.

3. The bill would permit even known poisons to be added to food without a showing of their functional value. Considering the inevitable residual risks attendant upon a safety evaluation—no matter how wide the margin of safety required by the evaluator—we believe that a showing of functional value should be required in all cases unless the additive is clearly a harmless substance.

The bill—assuming the term "safe for use" to be properly defined—would place upon this Department the grave responsibility of protecting the entire population from harm incident to the consumption of food containing additives, including active posions, over a lifetime. Our decisions necessarily must be based upon scientific data derived from tests made with the food additives on lower animals, generally small laboratory animals. Chemicals do not have identical actions on different species of animals. Thus, any attempt to determine the effect of an additive on man by translation from the effect of the additive on lower animals is, in the final analysis, a matter of informed scientific judgment. It is thus impossible to be absolutely sure from such tests that a new food additive will be completely safe for all humans under all conditions. The chance of harming the public is greatest in the case of products which are poisons, even though the amount appears to be small enough to be safe.

Hence, the law should make certain that no active poison be allowed in the food supply in any case where its use, or the particular level of use, is not clearly shown to result in a definite benefit to the producer or consumer.

DEPARTMENT OF AGRICULTURE,
Washington, D. C., July 12, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR CONGRESSMAN HARRIS: This is in reply to your request of January 16, 1957, for a report on H. R. 366, a bill to amend the Federal Food, Drug and Cosmetic Act for the protection of the public health, by prohibiting new food additives which have not been adequately pretested to establish their safe use under the conditions of their intended use.

The Department has no objection to the enactment of H. R. 366, insofar as it relates to the activities of this Department. We are not in a position to comment on the effects of the bill on the Department of Health, Education, and Welfare.

The bill defines "new food additive" as any substance used or intended to be used for any purpose in the manufacturing, packing, processing, preparation, or other fabrication of any food, or in the packaging, transporting, or holding of it, which (1) thus becomes or could reasonably be expected to become a component of such food and (2) is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of food, to be safe for use under the conditions of such use or intended use. The term does not include a pesticide chemical in or on a raw agricultural commodity, or, with respect to a particular food or class of foods, any substance to the extent to which its use for general consumption in the United States in or on such food or class of foods is properly authorized by the Food and Drug Administration or the Meat Inspection Branch of the United States Department of Agriculture. Under this bill a food would be deemed to be adulterated if, among other things, it bears or contains a new food additive which is unsafe under the bill. In determining whether a new food additive shall be deemed unsafe, the bill provides for the submission of pretesting data on a new food additive to the Secretary of Health, Education, and Welfare and the evaluation of such data by him. After the evaluation of such data, the said Secretary would be required to notify the person submitting such data whether the additive has been adequately pretested and thereby shown safe for use under the conditions of its intended use. After issuance of an opinion by the Secretary of Health, Education, and Welfare, either he or the person submitting the pretesting data would have a right to institute an action under the Declaratory Judgments Act.

Where a new food additive within the meaning of the bill is also an economic poison under the Federal Insecticide, Fungicide and Rodenticide Act, it is contemplated that in the usual case registration of an economic poison under the latter act will be withheld until the evaluation with respect to the safety of the new food additive by the Secreary of Health, Education, and Welfare has been completed.

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

TRUE D. MORSE, *Acting Secretary.*

FEDERAL TRADE COMMISSION,
Washington, March 29, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your letter of January 16, 1957, requesting an expression of the views of this Commission upon H. R. 366, 85th Congress, 1st session.

This bill would amend the Federal Food, Drug and Cosmetic Act with respect to the regulation of the use of additives in the manufacture and processing of food. The proposed amendment would not directly affect the functions or duties of this Commission and, therefore, while we appreciate the opportunity afforded by your request, it does not appear that there is any useful comment which we can furnish.

By direction of the Commission.

JOHN W. GWYNNE, *Chairman.*

DEPARTMENT OF JUSTICE,
OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D. C., July 9, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H. R. 366) to amend the Federal Food, Drug and Cosmetic Act for the protection of the public health by prohibiting new food additives which have not been adequately pretested to establish their safe use under the conditions of their intended use.

The bill would amend the act so as to provide that a food shall be deemed adulterated if it bears or contains a new food additive which is unsafe within the meaning of the act. The term "new food additive" would be defined as any substance used or intended to be used for any purpose in the manufacture, packing, processing, or preparation of any food, or in the packaging, transporting, or holding of it, which becomes or could reasonably be expected to become a component of such food, and is not generally recognized, among experts qualified to evaluate the safety of food, to be safe for use under the conditions of such use or intended use. The bill would establish procedures by which the Secretary of Health, Education, and Welfare would determine whether in his opinion any new food additive had been adequately pretested and shown safe for use. After an opinion had been issued by the Secretary, either the Secretary or the person interested in the new food additive would have the right to institute an action under the Declaratory Judgments Act to secure a declaration as to whether the additive had been adequately pretested and shown safe for use.

Whether legislation of this general nature should be enacted involves a question of policy concerning which this Department prefers to make no recommendation. There are certain provisions of the bill here under consideration, however, which it is believed should be amended.

The provision for an action under the Declaratory Judgments Act would amount to a de novo trial in a district court to review the expert judgment and discretion of the Secretary with respect to his determination as to safety. Such procedure would be a departure from the usual pattern whereby matters committed to expert administrative determination are subjected only to judicial review on the administrative record.

While paragraph (c) in the proposed new section 409 in effect states that the Secretary is to determine whether the additive is "thereby shown safe for use," the definition of "unsafe" in section 409 (a) does not prescribe that an additive found to be unsafe shall render it or a food containing it "adulterated." It provides only that the applicant's pretesting data shall be submitted to the Secretary and that the Secretary shall have an opportunity to evaluate such data. There is no provision for an order by the Secretary that the additive has not been shown to be safe.

The bill contains a provision which would require the Secretary to issue a list of substances which are in his opinion generally recognized to be safe for use, which list must be published in the Federal Register. It would further provide that from time to time, on at least 60 days' notice published in the Federal Register, the Secretary could remove any such substance from the list or modify the quantities or conditions of use specified. The inclusion of a substance in the list would be conclusive evidence that the substance is generally recognized among qualified experts as being safe for use under the conditions specified. This would have the effect of administratively removing these substances from the coverage of the act. The omission or removal of a substance from the list would not create any presumption that the substance is not generally recognized by qualified experts as being safe for use under specified conditions.

This provision might have the effect of giving to proponents of an additive which is removed from the list the advantage of judicial review of such agency action under section 10 of the Administrative Procedure Act. Yet, if proponents lost on review, there still would be no presumption that the substance was not generally recognized as being safe, and proponents might thereafter still have available the declaratory-judgments provision of the bill.

It is also noted that the bill does not provide any procedure whereby the Secretary might, on his own initiative, undertake proceedings to reverse any previous adverse ruling under the Declaratory Judgments Act on the basis of new scientific data.

The Bureau of the Budget has advised that there is no objection to the submission of this report.

Sincerely,

WILLIAM P. ROGERS,
Deputy Attorney General.

THE SECRETARY OF COMMERCE,
Washington, D. C., July 22, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter is in reply to your request dated July 10, 1957, for the views of this Department with respect to bills H. R. 366, H. R. 4014, H. R. 6747, H. R. 7700, H. R. 7798, H. R. 7938, H. R. 8112, and H. R. 8390, all relating to chemical food additives.

Under the present law the Department of Health, Education, and Welfare polices the safety of the food supply primarily by relying upon sections 402 and 406 of the Food, Drug and Cosmetic Act. These sections deal with the control of adulterated food, and of food deemed to be unsafe because it contains added poisonous or deleterious substances.

As it has been administered by the Department of Health, Education, and Welfare the present law has worked well. Accordingly, it is generally felt that there is no demonstrated necessity for sweeping changes in the existing law.

However, present law permits corrective action only after a product has been marketed and when the Secretary of Health, Education, and Welfare can show that the additive is poisonous or deleterious. There is no general recognition that this situation represents distinct exposure to the unwarranted introduction into the feed supply of some harmful material.

Generally these bills would require a person manufacturing a new chemical additive to be used in food to submit his test data, along with other relevant matter demonstrating its safety, to the Secretary before the additive can be shipped in interstate commerce for use in food.

We believe that well drafted legislation for this purpose would constitute a constructive addition to the existing law. The existing practice of clearing new additives with the Food and Drug Administration, which has been followed for a number of years (even though not required), would continue, and we feel that most disputes as to the safety of an additive would be informally resolved.

It is noted that H. R. 366 would provide for use of the Declaratory Judgments Act in the enforcement of its provisions. This Department has no preference between this enforcement procedure and the other procedures which have been suggested in legislation proposed for these purposes. We recommend, however, that your committee adopt the enforcement procedure which public hearings develop as being the method best calculated to provide maximum protection to the public with the most expeditious procedural handling.

These proposals do not provide for the automatic continued use of additives presently in use. At least one of them (H. R. 366) provides that the Secretary of Health, Education, and Welfare would be required to issue a list of substances which, in his opinion, are generally recognized to be safe under the specific conditions of use. Thus, many substances which have been used in the food industry over a long period of years could be left in a state of uncertainty as to whether they could be lawfully used without going through the testing and clearance procedure of the proposed enactment. This uncertainty would be likely to create a hardship on certain industry groups. We feel that this is particularly true of the packaging industries generally; and that to include in the scope of the pretesting requirements the many components of and the many substances necessary to the manufacture of paper and paperboard, containers, glass, resins and plastics, and cooperage products, which substances have been used for many years, is not warranted. Since a major question with respect to packaging materials is whether or not they will become components of the food packaged, it would appear that any such legislation should provide for listing of all such items currently in general use which are in the Secretary's opinion generally recognized as not likely to come into contact with or migrate into food under the specified conditions of use. It is to be hoped that such listing could be blanket in character, with specific mention of those excepted because of doubt as to their suitability. Of course, provision should also be made for inclusion in such list of any item likely to become a component of food if considered not to be harmful.

The Department considers highly undesirable any blanket requirement such as is contained in H. R. 4014 that a chemical additive be shown to serve a purpose which will be useful to the consuming public before its use is permitted. Such a restriction would be undesirable and might impose a great burden upon industry without any countervailing benefit to the consuming public. For example, various manufacturers in the food industry use such items as antifoam agents, chemical preservatives, wetting agents, germicidal agents, sequestering agents, etc. These additives are extremely useful for the purposes of the food processors but they might not meet the criterion of usefulness to the consuming public. The Department believes that use of any additives nontoxic in nature should be permitted without restriction and, if a material is toxic in nature, its use should be permitted for useful purposes if its safety in the proposed uses is established. Provisions such as those contained in H. R. 6747 would appear to be satisfactory for this purpose.

Since the impact of the legislation will be substantial, the provisions of the legislation should not take effect within less than 1 year except as to substances which have been sooner established to be toxic in nature.

The Department recommends the enactment of legislation for this purpose, subject to consideration of the above comments.

The Bureau of the Budget has advised that it would interpose no objection to the submission of this report to your committee.

Sincerely yours,

SINCLAIR WEEKS, *Secretary of Commerce.*

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D. C., June 26, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: This is in response to your requests for reports on H. R. 366, H. R. 4014, H. R. 4432, H. R. 6747, H. R. 7700, and H. R. 7798. These bills all have the purpose of protecting the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

The Bureau of the Budget believes that there is a need for the enactment of legislation having the purpose of requiring the pretesting of chemical additives used in or on foods.

One of the subject bills, H. R. 6747, is identical to the draft bill prepared by the Department of Health, Education, and Welfare. There are many points of difference between H. R. 6747 and other bills. One such difference concerns the question of whether the responsibility for the determination of the safety of foods should rest with the Secretary of Health, Education, and Welfare, subject to the right of judicial review on the administrative record, or whether a different approach should be used involving an action under the Declaratory Judgments Act which would amount to a de novo court trial to review the judgment and discretion of the Secretary with respect to his determination as to safety. We understand that the latter approach is contained in H. R. 366, one of the subject bills. There appears to be no necessity for initiating such a departure from the usual pattern consisting in administrative determination subject to judicial review based upon the administrative record. In this connection we not that the Department of Justice in its report on H. R. 366 states its belief that the de novo court-trial provision of this bill should be amended.

In our view the procedural and other provisions of H. R. 6747 provide a sound and constructive approach to the problems in this area. Accordingly, the Bureau of the Budget favors the enactment of H. R. 6747 in preference to the other subject bills.

Sincerely yours,

ROBERT E. MERRIAM, *Assistant Director.*

FEDERAL TRADE COMMISSION,
Washington, May 15, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your letter of April 11, 1957, inviting comment upon H. R. 6747, 85th Congress, 1st session, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of chemical additives which have not been adequately tested to establish their safety.

As indicated by its title, the bill would amend the Federal Food, Drug and Cosmetic Act so as to regulate and control the use in food of "chemical additives" as that term is defined in the bill. This proposed legislation, if enacted, would be administered by the Department of Health, Education, and Welfare and would not directly affect the duties and functions of the Federal Trade Commission.

While we appreciate the opportunity afforded for comment, in view of the lack of direct effect upon the duties of this agency and the fact that we have not been immediately concerned with many of the technical and scientific problems involved, it is not believed that there is any useful comment that we can offer.

By direction of the Commission.

JOHN W. GWYNNE, *Chairman.*

DEPARTMENT OF AGRICULTURE,
Washington, D. C., July 12, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR CONGRESSMAN HARRIS: This is in reply to your request of April 11, 1957, for a report on H. R. 6747, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of chemical additives which have not been adequately tested to establish their safety.

The Department has no objection to the enactment of the proposed legislation, insofar as it relates to the activities of this Department. We are not in a position to comment on the effects of the proposed legislation on the Department of Health, Education, and Welfare.

The proposed bill defines "chemical additives" as any substance the intended use of which results or may result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, except that the term does not include a pesticide chemical in or on a raw agricultural commodity or any substance used in accordance with a sanction or approval granted under the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act prior to the enactment of this proposed legislation. The bill further provides that nothing in the Federal Food, Drug and Cosmetic Act shall be construed to exempt any meat or meat food product from any requirement imposed or by or pursuant to that Meat Inspection Act. The legislative proposal would also amend the definition of "food" to include chemical additives. In addition, the proposed bill states that a chemical additive shall be deemed to be unsafe unless an exemption has been granted or there is in effect, and the use or intended use of such additive is in conformity with, a regulation issued under the provisions of the bill announcing the conditions under which the additive may be used. It sets forth the procedures for the issuance of regulations announcing the condiditions under which additives may be safely used or granting exemptions.

It is our interpretation of the definition of "chemical additive" that such definition would not normally include an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act where the labeling and directions for use are such that contamination of food may not be reasonably expected.

We interpret this bill as giving to the Department of Health, Education, and Welfare jurisdiction over the safety of a chemical additive in or on food, and the Department of Health, Education, and Welfare, will have jurisdiction over

a chemical additive that is an economic poison under the Federal Insecticide, Fungicide and Rodenticide Act to the extent that the Department of Health, Education, and Welfare will determine whether the chemical additive [economic poison] is safe as a food or on a food. Therefore, in dealing with a product that would be both a chemical additive and an economic poison, this Department will not accept for registration purposes directions for use which are likely to result in the product becoming a part of food until the Department of Health, Education, and Welfare has determined the conditions under which such product might be safely used in or on a food. Where an economic poison presently registered under the Federal Insecticide, Fungicide and Rodenticide Act is deemed to be a chemical additive under this bill, primary jurisdiction over the food uses of such product will be in the Department of Health, Education, and Welfare.

From the enforcement standpoint it is evident that occasionally both this Department and the Department of Health, Education, and Welfare might conduct examination of a chemical which would be subject to this bill and to the Federal Insecticide, Fungicide and Rodenticide Act. This would not appear to create any particular difficulty because the investigations would not be parallel. The investigation made by the Department of Health, Education, and Welfare would cover the food uses of the additive and the investigation made by this Department would cover such other uses as would be subject to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act. In addition, it is anticipated that close liaison will be established, as it has been in the past, to facilitate the working out of matters coming within the jurisdiction of each Department.

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

TRUE D. MORSE, *Acting Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
May 1, 1957.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This replies to your request of April 11, 1957, for a report on H. R. 6747, a bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of chemical additives which have not been adequately tested to establish their safety.

The bill incorporates the provisions of a draft bill submitted by this Department to the Congress on April 5, 1957. We enclose a copy of our letter of April 5 to the Speaker of the House, together with the attachments thereto.

For the reasons stated in the letter to the Speaker and in the accompanying explanation of the bill, we urge enactment of H. R. 6747. If there is further information we can supply on the matter, please feel free to call upon us.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, April 5, 1957.

HON. SAM RAYBURN,
Speaker of the House of Representatives,
Washington, D. C.

DEAR MR. SPEAKER: Enclosed for your consideration is a draft of a bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of chemical additives which have not been adequately tested to establish their safety.

This bill deals with the problem of safety to the consumer arising from the widespread and increasing use of chemicals in modern food-processing technology. Within the last 20 years, hundreds of chemical substances have been added to foods and the search for new chemicals to improve foods is being accelerated. Many have not been subjected to adequate scientific investigation to determine their safety. It is essential to the public health that we know that proposed ingredients are safe before they are used in food. The hazards are too great to justify any other procedure.

Under existing law, poisonous and deleterious substances may not be added to food in any amounts unless they are required in production or cannot be avoided by good manufacturing practice. When they are so required or unavoidable, the Department is authorized to establish safe tolerances for them. But no action can be taken to stop the use of a chemical until the Government can prove that it actually is a poisonous or deleterious substance. This proof may require 2 years of laboratory experimentation with small animals, and while it is being obtained the chemical can be used in food.

The deficiencies in the present law were studied by a House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics (Delaney committee). The committee, on June 30, 1952, recommended "that the Federal Food, Drug and Cosmetic Act be amended to require that chemicals employed in or on foods be subjected to substantially the same safety requirements as now exist for new drugs and meat products" H. Rept. No. 2356, 82d Cong., 2d sess.). To accomplish in part the recommendations of the committee, the Pesticide Chemicals Amendment of the Federal Food, Drug and Cosmetic Act was enacted in 1954 (Public Law 518, 83d Cong.). This provided a convenient method for establishing safe tolerances for residues of pesticide chemicals on raw agricultural commodities.

The present draft bill—which resembles some of the bills, introduced in the 84th Congress, on which a subcommittee of the House Committee on Interstate and Foreign Commerce has held hearings—would be a further step in accomplishing the objectives of the committee report, in that it would provide a similar convenient method for establishing safe conditions for employing chemicals in food production and processing and related activities.

The bill would furnish an adequate pretesting requirement. It would permit this Department, on its own initiative or at the request of any interested person, to issue a regulation announcing the conditions under which an additive may be used safely. The regulation could issue only on the basis of scientific evidence that the proposed use would be safe. (The evidence generally would be supplied by the proponent of the use proposed for the chemical, that is, the chemical manufacturer.) Unless the additive were found not to be a poisonous or deleterious substance, it would have to have functional value before even safe amounts would be tolerated in food.

Distribution and use of an additive under conditions other than those announced in an applicable regulation would be prohibited. The seizure, injunction, and prosecution provisions in the present law would be applicable in case of violations. Additives that are generally recognized as safe by appropriately qualified experts are exempted by the bill.

The provisions of this bill are patterned after those of Public Law 518, 83d Congress, above mentioned. That amendment provides for the establishment of safe tolerances for residues of a special class of chemical additives (pesticides) on crops and other raw agricultural commodities. Our experience with Public Law 518 shows that it is workable and fair.

Controversies with regard to regulations would be resolved by procedures now provided in the Administrative Procedure Act and the Food, Drug and Cosmetic Act. Among other things, the draft provides for questions to be referred, in appropriate circumstances, to an advisory committee of experts selected by the National Academy of Sciences, as does Public Law 518, 83d Congress.

The bill would authorize the appropriation of such sums as may be necessary for the administration of the legislation. We estimate that $200,000 would be required the first year.

The enclosed memorandum contains a more detailed summary of the principal features of the bill.

We shall appreciate it if you would refer the enclosed draft bill and accompanying explanation to the appropriate committee for consideration.

The Bureau of the Budget advises that it perceives no objection to the presentation of this legislative proposal to the Congress.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

A BILL To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of chemical additives which have not been adequately tested to establish their safety

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Chemical Additives Amendment of 1957."

SEC. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraph:

"(s) (1) The term 'chemical additive' means, except as otherwise provided in subparagraph (2), any substance the intended use of which results or may result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended to preserve or alter food or for any other purpose in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any radioactive material intended for any such use or as a source for the irradiation of food), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use.

"(2) Such term does not include (A) a pesticide chemical in or on a raw agricultural commodity, or a pesticide chemical when intended solely for use in the production, storage, or transportation of any raw agricultural commodity; or (B) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act or to the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 et seq.)."

SEC. 3. Section 201 (f) of such Act is amended to read as follows:

"(f) The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, (3) articles used for components of any such article, and (4) chemical additives."

SEC. 4. (a) Clause (2) of section 402 (a), as amended, of such Act is further amended to read as follows:

"(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a chemical additive) which is unsafe within the meaning of section 406; or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408; or (C) if it is, or it bears or contains, any chemical additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity."

(b) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

SEC. 5. Chapter IV of such Act is amended by adding at the end thereof the following new section:

"CHEMICAL ADDITIVES

"UNSAFE CHEMICAL ADDITIVES

"SEC. 409. (a) A chemical additive shall, with respect to any particular use or intended use of such additive, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) the use or intended use of such additive conforms to the terms of an exemption which is in effect pursuant to subsection (j) of this section; or

"(2) there is in effect, and the use or intended use of such additive is in conformity with, a regulation issued under this section announcing the conditions (including any directions or other labeling or packaging requirements contained in such regulation) under which such additive may be safely used.

While such a regulation relating to a chemical additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) or (2) (C) of section 402 (a).

"PETITION TO ESTABLISH SAFETY

"(b) (1) Any interested person may, with respect to any intended use or uses of a chemical additive, file with the Secretary a petition proposing the issuance of a regulation announcing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to setting forth the regulation proposed by the petitioner and stating reasonable grounds in support of the petition, contain or be accompanied by—

"(A) the name and all pertinent information concerning such chemical additive, including where available its chemical identity and composition;

"(B) (i) a statement of the conditions of the proposed use or uses of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling; and (ii) all relevant data bearing on the functional value of such additive;

"(C) a full description of the methods used in, and the facilities and controls used for, the production of such additive;

"(D) a description of practicable methods for quantitative determination of such additive, and its breakdown or reaction products, in or on food referred to in the petition; and

"(E) full reports of investigations made with respect to the toxicity or other potentiality for harm of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish samples of the chemical additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

"(4) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

"ACTION ON THE PETITION

"(c) (1) As soon as practicable after the filing of the petition, and in no event later than the expiration of the applicable period specified in paragraph (2) of this subsection, the Secretary shall, in the absence of a prior referral or request for referral to an advisory committee made pursuant to this section—

"(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) announcing, with respect to one or more proposed uses of the chemical additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use or uses), and shall notify the petitioner of such order; or

"(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

"(2) The order required by paragraph (1) (A) or (B) of this paragraph shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"(3) No such regulation shall issue unless the scientific data submitted or otherwise before the Secretary establish that the proposed use of the chemical additive, under the conditions of use to be specified in the regulation, will be without hazard to the health of man or other animals consuming any food which is or may, directly or indirectly, be affected by such use, including any food that is yielded by or derived from an animal or plant into which a chemical additive has been introduced by feeding or otherwise, and that such proposed use has functional value; except that the Secretary shall not take functional value into account if he finds that such additive is not a poisonous or deleterious substance.

"(4) In determining, for the purposes of this section, whether a proposed use of a chemical additive is safe, the Secretary shall consider among other relevant factors—

"(A) the probable consumption of the additive and of any food in or on which it is intended to be used as a component;

"(B) the cumulative effect of such additive in the diet of man or other animals concerned, taking into account any chemically or pharmacologically related substance or substances in such diet where relevant because of their use in or on foods; and

"(C) appropriate safety factors for transposing animal experimentation data to practical use in appraising the hazard to man or to other animals expected to consume food that will or may be affected by such chemical additive.

"REGULATION ISSUED ON SECRETARY'S INITIATIVE OR UPON REQUEST

"(d) The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation announcing, with respect to any particular use or uses of a chemical additive, the conditions under which such additive may be safely used. After the expiration of thirty days after publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal, unless within such thirty-day period a person who is entitled to file a petition under subsection (b) with respect to such additive requests that the proposal, or any question of fact raised thereby, be referred to an advisory committee appointed pursuant to this section.

"REFERENCE TO ADVISORY COMMITTEE

"(e) (1) Within the applicable time limit specified in subsection (c) for action by the Secretary upon a petition but in no event more than thirty days after publication of an order issued pursuant to such subsection, or within thirty days after publication of a proposal for issuance of a regulation pursuant to subsection (d), the petitioner (or, in the case of a proposal under subsection (d), any person entitled to file a petition with respect to the additive involved) may request that such petition or order thereon, or such proposal, or any question of fact raised by such petition, order, or proposal, be referred to an advisory committee. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee of competent experts in accordance with and subject to the provisions of section 408 (g) and shall refer such petition, order, or proposal, or such question of fact, as the case may be, to such committee and furnish it with all the data before him: *Provided*, That the requirement of representation from land-grant colleges on the committee shall not apply and that in the event of the inability or refusal of the National Academy of Sciences to act the Secretary shall select the members of the committee. A person who has filed a petition or who has requested the referral of a proposal to an advisory committee, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it.

"(2) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall confirm or modify any order theretofore issued or, if no such order has been issued, shall establish a regulation announcing, with respect to any particular use or uses of the chemical additive involved, the conditions under which such additive may be safely used or refuse to establish a regulation.

"(3) The Secretary may by regulation condition referrals to advisory committees pursuant to this subsection upon the payment, by the person requesting the referral, of fees to defray the costs arising by reason of such referrals. Such regulations may provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection. Such fees, including advance deposits to cover such fees, shall be available, until expended, for paying (directly or by way of reimbursment of the applicable appropriation) the expenses of advisory committees under this subsection and other expenses arising by reason of referrals to such committees, and for refunds pursuant to this paragraph.

"PUBLICATION AND EFFECTIVE DATE OF ORDERS

"(f) Any order, including any regulation established by such order, issued under subsection (c), (d), or (e) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if after issuance of such order the petition or any question of fact raised thereby is referred to an advisory committee pursuant to subsection (e) or if a hearing is sought with respect to such order pursuant to subsection (g).

"OBJECTIONS AND PUBLIC HEARING

"(g) Within thirty days after publication, any person adversely affected by an order made pursuant to subsection (c), (d), or (e) of this section may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections: *Provided*, That if, after issuance of an order under subsection (c), the right of referral to an advisory committee is invoked, only the order thereafter issued pursuant to subsection (e) after receipt of the advisory committee's report shall be subject to such objections and public hearing. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing if relevant and material, subject to the provisions of section 7 (c) of the Administrative Procedure Act (5 U. S. C. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and shall by published order either confirm or modify the order to which objections have been filed. Such new order shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"JUDICIAL REVIEW

"(h) In a case of actual controversy as to the validity of any order issued under subsection (g), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review thereof in accordance with, and subject to, the applicable provisions of section 408 (1).

"AMENDMENT OR REPEAL OF REGULATIONS

"(i) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations, including the appointment of advisory committees and the procedure for referring petitions or proposals to such committees.

"EXEMPTIONS FOR INVESTIGATIONAL OR OTHER USE

"(j) The Secretary (1) shall promulgate regulations providing for exempting from the requirements of this section any chemical additive, and any food bearing or containing such additive, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such additive; and (2) may by regulation exempt any other chemical additive, or any food bearing or containing it, or both, when in his opinion such exemption is consistent with the public health."

SEC. 6. Section 301 (j) of such Act is amended by inserting "409" after "404,".

SEC. 7. (a) Except as otherwise provided in this section, this Act shall take effect on the one hundred and eightieth day (hereinafter referred to as the effective date of this Act) after the date of its enactment.

(b) Any interested person desiring to do so may at any time, after the date of enactment and prior to the effective date of this Act, file a petition as provided in subsection (b) of section 409 of the Federal Food, Drug and Cosmetic Act, as enacted by section 5 of this Act, in which event the provisions of such section 409, and of section 201 (s) and section 301 (j) of such Act as amended by this Act, shall become effective immediately as applied to such petition and to proceedings thereon; but nothing in this subsection shall be construed to accelerate the effective date of the remaining provisions of this Act.

(c) Where a chemical additive was in use for one or more purposes immediately prior to the date of enactment of this Act, the amendments to sections 402 (a) and 406 (a) of the Federal Food, Drug and Cosmetic Act made by section 4 of this Act shall not, as applied to such preexisting use or uses of such additive, become effective until—

(1) the final establishment of a regulation or exemption relating to such use or uses pursuant to section 409 of such Act or the final denial of a petition for such regulation or exemption (without, in either case further opportunity for referral to an advisory committee, for an administrative hearing, or for judicial review); or

(2) if earlier, the expiration of either (A) the one-year period beginning on the date following the effective date of this Act, or (B) such additional period (not extending beyond two years after the effective date of this Act) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such additional period.

SEC. 8. There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, such sums as may be necessary for the administration of this Act.

SEC. 9. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 et seq.).

PRINCIPAL FEATURES OF DRAFT BILL TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG AND COSMETIC ACT TO PROHIBIT THE USE IN FOOD OF CHEMICAL ADDITIVES WHICH HAVE NOT BEEN ADEQUATELY TESTED TO ESTABLISH THEIR SAFETY.

OBJECTIVES

The major purposes of the bill is to fill a gap in protection of consumer health under the Federal Food, Drug and Cosmetic Act by prohibiting the distribution and use of chemicals as intentional food additives, or for any other purpose which may directly or indirectly result in the chemical's finding its way into or affecting a food, unless the intended use of the chemical is generally recognized along competent experts as safe for the consumer of this food or unless such use has first been found to be safe by the Department of Health, Education, and Welfare on the basis of adequate scientific test data (usually to be furnished by the sponsor). An additional purpose is to advance food technology by permitting use of a technically poisonous or deleterious substance as a food additive within an officially established safe tolerance when such use is found to have functional value, whereas existing law bars such substances even at a safe level unless required in production or unavoidable by "good manufacturing practice."

SCOPE OF THE BILL

1. The bill covers only so-called intentional additives, i. e., substances the intended use of which results or may result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of a food, thus excluding from the scope of the bill wholly accidental additives, i. e., those which are neither intended as components of food nor have the potential, under the conditions of their intended use, of becoming a component of food or affecting its characteristics. The principal examples of additives covered by the bill are chemicals used in connection with food production, preservation, manufacture, packing, processing, packaging, transporting, or holding food, and radioactive materials used in food processing or for subjecting food to radiation.

2. In order to bring a chemical within the scope of the bill, it would have to be one which is not generally recognized among competent experts as having

been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use. Substances used in accordance with a sanction or approval granted prior to the enactment of this bill pursuant to the Federal Food, Drug and Cosmetic Act or to the Meat Inspection Act would likewise be excluded. (This, of course, would not prevent rescission of such a sanction or approval, and consequent inclusion of the additive under the bill, if the particular use of the additive is subsequently found to be toxic or of doubtful safety.) The Secretary would also be directed to provide by regulation for exempting chemical additives, and other foods containing such additives, from the requirements of the bill when intended solely for investigational use by experts; and he would be authorized to exempt by regulation any other chemical additive, or a food containing it, when in his opinion such an exemption is consistent with the public health.

3. Pesticide chemicals in or on raw agricultural commodities, or when intended solely for use in the production, storage, or transportation of such commodities, would likewise be excluded from the scope of the bill, the use of such additives being already safeguarded by the Pesticide Chemicals Amendment Public Law 518, 83d Cong.). Moreover, in consonance with a regulation now in force, the requirements of the bill would not apply to a pesticide residue which, after processing of a raw agricultural commodity by cooking, freezing, dehydrating, or milling, is unavoidably left in the processed food, where the concentration of the pesticide in the processed food when ready to eat does not exceed the tolerance allowed under the Pesticide Chemicals Amendment with respect to the raw agricultural commodity and that commodity met the requirements of the amendment.

4. In view of the meshing of the Federal Food, Drug and Cosmetic Act (sec. 902 (d)) and the Meat Inspection Act, the bill expressly provides that it shall not be construed to relieve any person or any meat or meat food-product from compliance with any requirement of that act. Thus, a chemical additive intended for use in meat or meat products would have to comply with regulations under this bill before being shipped to an establishment subject to the Meat Inspection Act but would not be allowed in meat until it likewise meets requirements under that act. (Regulations under the latter act are not limited to considerations of safety.) Nor is the bill intended to relieve from requirements imposed by other laws, such as the Federal Insecticide, Fungicide and Rodenticide Act or the Atomic Energy Act of 1954.

MEANS OF EFFECTUATING THE BILL'S OBJECTIVES

1. A food—which by definition would include an intentional chemical additive as above described—would be deemed to be adulterated and hence within the prohibitions and civil and criminal sanctions of the Federal Food, Drug and Cosmetic Act, if it is, or if it bears or contains, a chemical additive which is unsafe within the meaning of a new section, i. e., section 409, to be added to the act by the bill. Under such new section, the chemical additive would be deemed to be unsafe with respect to any particular use or intended use of such additive unless such use or intended use either conforms to the terms of an exemption granted by the Secretary or to a regulation issued under this section and announcing the conditions under which such additive may be safely used. (Sec. 406 (a) of the act, which now prohibits or restricts the use of added poisonous or deleterious substances in food, would become inapplicable to chemical additives falling within the scope of the bill.)

2. A proposal for the establishment of a regulation as to the safety of a chemical additive could be made either by way of a petition filed by any interested person (presumably the manufacturer of the additive in most cases), with submission of full test data, samples of the additive (when requested), etc., or by the Secretary on his own initiative or on the request of any interested person. A regulation actually issued might or might not be the same as that proposal. The petitioner (or any person entitled to file such a petition where the proposal is made by the Secretary) could require that, before action by the Secretary and within certain limits after such action, the petition or other proposal, or any question of fact raised thereby, be submitted for study and recommendation to an advisory committee appointed by the Secretary from among experts selected by the National Academy of Sciences. Likewise, the Secretary could on his own initiative refer the proposal or any subsidiary question of fact to such an advisory committee. The referral of a matter to an

advisory committee on request could, by regulation, be conditioned on the payment of fees to defray the cost occasioned by such referrals.

3. No regulation permitting a proposed use of a chemical additive could be issued unless the scientific data submitted to or otherwise before the Secretary establish that such use of the additive will be without hazard to the health of man or other animals consuming any food which may directly or indirectly be affected by such use. This would include any food that is yielded by, or derived from, an animal or plant into which a chemical additive has been introduced by feeding or otherwise. For example, in the case of fertilizer to be sprayed or on otherwise to be introduced into a plant, the safety of any residue of the additive or its breakdown or reaction products which will ultimately find their way into food derived from such plant and consumed by man or animal would have to be established. Similarly, in case of an additive introduced into a food-producing animal directly or through introduction into its environment or food, it would have to be established that the edible flesh or the animal or food products derived from the living animal (such as milk, eggs, etc.) are safe for the human being or animal whose diet will ultimately be affected. In determining safety, the Secreary would have to take into account the total lifetime diet of man or other animals involved, as affected by such additive and any chemically or pharmacologically related substances in the diet. Moreover, the data before the Secretary would have to establish that the additive has functional value, unless the Secretary finds that the additive is not a poisonous or deleterious substance.

4. Any person adversely affected by a regulation issued by the Secretry, or by his refusal to issue a regulation, could file objections to the Secretary's order, stating reasonable grounds for such objections, and would thereupon be entitled to a public hearing. The Secretary's order issued after such hearing would have to be based solely on substantial evidence of record at the hearing, including any report or recommendations of an advisory committee to which a referral had been made. In a case of actual controversy as to the validity of any order issued after hearing, any person who would be adversely affected by such order could obtain judicial review thereof in a United States court of appeals in accordance with the provisions now applicable to regulations issued under the pesticide chemicals amendment.

5. The Secretary would be required to prescribe similar procedures for amending or repealing regulationsc issued under the bill.

EFFECTIVE DATES AND TRANSITIONAL PROVISIONS

1. In general, the bill would take effect on the 180th day after its enactment. However, any interested person would be permitted to start the procedure for the issuance of a regulation as to the safety of a particular additive before such effective date, in which event the procedure would be carried to completion without delay but the additive would not have to conform to the regulation until such effective date.

2. In order to allow a reasonable period for industry adjustment in the case of chemical additives already in use prior to the enactment of the bill, those provisions of the bill under which a food (including a chemical additive, which is deemed a food) would be deemed adulterated unless a safety clearance regulation is issued and complied with, would not become effective until such a regulation is finally denied or is acctually issued and has become finally established or, if earlier, until the expiration of either 1 or 2 years (as determined by the Secretary in the light of the risk to public health) following the 180-day effective date of the bill.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
July 12, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your request for a report on H. R. 7700, a bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food.

The provisions of this bill are identical with the bills covered by our report on H. R. 4014 and H. R. 4432. For the reasons stated in that report, we recom-

mend against enactment of the present bill and, in lieu thereof, recommend enactment of H. R. 6747.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

DEPARTMENT OF AGRICULTURE,
Washington, D. C., July 12, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR CONGRESSMAN HARRIS: This is in reply to your request of May 24, 1957, for a report on H. R. 7700, a bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food.

The Department has no objection to the enactment of H. R. 7700, insofar as it relates to the activities of this Department, provided it is amended as indicated herein. We are not in a position to comment on the effects of the bill on the Department of Health, Education, and Welfare.

The bill defines "chemical additive" as any substance which (1) is intended for use in food or in a collateral way, for example, in packaging materials, if such use is likely to result in the contamination of food; and (2) is not generally recognized among experts as having been adequately tested to show either that it is not poisonous or deleterious, or that it is safe for the intended use. However, the definition excludes pesticide chemicals used in the production, storage, or transportation of raw agricultural commodities. The bill provides that any person may file with the Secretary of Health, Education, and Welfare an application containing scientific data for the purpose of establishing that a proposed chemical additive is not a poisonous or deleterious substance, or if it is, that it is safe and required for its intended use, and that the intended use of the chemical additive will serve a purpose which will be useful to the consuming public. Within a specified period after the filing of the application, the said Secretary is required to issue an order approving the application or refusing to approve the application. Provision is made for review of the finding in the event the application is denied. The said Secretary, by regulation, shall require the payment of such fees for the performance of the Secretary's functions under this statute as will be in the aggregate, in his judgment, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for such function. The legislation is to take effect 6 months after the date of its enactment.

The definition of "chemical additive" should exempt any substance approved prior to the enactment of the bill pursuant to the provisions of the Meat Inspection Act of March 4, 1907, as amended and extended (34 Stat. 1260, as amended and extended; 21 U. S. C. 71 et seq.). In addition, in order that it may be made clear that this bill is not intended to have any amendatory effect upon section 902 (b) of the Federal Food, Drug and Cosmetic Act (21 U. S. C. 392), an additional provision should be added to the bill reading as follows:

"Nothing in this act shall be construed to exempt any meat or meat-food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, as amended and extended (34 Stat. 1260, as amended and extended; 21 U. S. C. 71 et seq.)."

Propoesd section 409 (a) of H. R. 7700 provides that no person shall introduce or deliver for introduction into interstate commerce any chemical additive, unless the use of such chemical additive has been approved pursuant to this section. From the enforcement standpoint it is evident that occasionally both this Department and the Department of Health, Education, and Welfare might conduct examination of a chemical which would be subject to this bill and to the Federal Insecticide, Fungicide and Rodenticide Act. This would not appear to create any particular difficulty because the investigations would not be parallel. The investigation made by the Department of Health, Education, and Welfare would cover the food uses of the additive and the investigation made by this Department would cover such other uses as would be subject to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act.

In dealing with a product that would be both a chemical additive and an economic poison, this Department would not accept for registration purposes directions for use which are likely to result in the product becoming a part of food until the Department of Health, Education, and Welfare has approved the use of such product in or on food. Where an economic poison presently registered

under the Federal Insecticide, Fungicide and Rodenticide Act is deemed to be a chemical additive under this bill, primary jurisdiction over the food uses of such product will be in the Department of Health, Education, and Welfare.

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

TRUE D. MORSE, *Acting Secretary.*

DEPARTMENT OF JUSTICE,
Washington, D. C., July 24, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice relative to the bill (H. R. 7700) to protect the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food.

Section 1 of the bill would amend the definition section of the Federal Food, Drug and Cosmetic Act so as to add to it a definition of the term "chemical additive." As defined, a chemical additive would be any substance (1) intended for use as a food or to preserve or alter any characteristic of a food or intended for any other purpose in producing, processing, packing, etc., food if such use is likely to result in the contamination of food; and (2) not generally recognized by experts as having been adequately tested with respect to poisonous or deleterious effects.

Section 5 of the bill would add to the act a new section designated "409." This section would prohibit the introduction or delivery for introduction into interstate commerce of any chemical additive unless the use of such additive has been approved pursuant to the section. Upon application for the issuance of an order approving the use of a chemical additive, the Secretary of Health, Education, and Welfare may issue an order approving or disapproving such use. When he deems such action advisable, or when requested by the applicant, the Secretary shall seek the advice and recommendations of an advisory committee composed of experts. Orders issued under this section are appealable to the district courts of the United States.

The remaining provisions of the bill are incidental to and in implementation of the sections described generally above.

Whether this legislation should be enacted involves questions of policy concerning which the Department of Justice prefers to make no recommendation.

The Bureau of the Budget has advised that there is no objection to the submission of this report.

Sincerely,

WILLIAM P. ROGERS,
Deputy Attorney General.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, July 23, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter is in response to your request of June 4, 1957, for a report on H. R. 7798, a bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food.

This bill is a revision of H. R. 4014, and the views expressed in our report on that bill and H. R. 4432 are equally applicable here, except as stated below.

1. H. R. 7798 specifies in the proposed section 409 (b) (2) that an application for the issuance of an order approving the use of a chemical additive shall contain reports of investigations to determine the additive's carcinogenicity. In section 409 (d), it specifies that the Secretary "shall not approve for use in food any chemical additive found to induce cancer in man or, after tests, found to induce cancer in animals."

We, of course, agree that no chemical should be permitted to be used in food if, as so used, it may cause cancer. We assume that this, and no more, is the aim of the sponsor. No specific reference to carcinogens is necessary for that

purpose, however, since the general requirements of this bill give assurance that no chemical additive can be cleared if there is a reasonable doubt about its safety in that respect.

On the other hand, the above-quoted provisions are so broadly phrased that they could be read to bar an additive from the food supply even if it can induce cancer only when used on test animals in a way having no bearing on the question of carcinogenicity for its intended use. This, we think, would not be in the public interest. Scientists, I am advised, can produce cancer in test animals by injecting sugar in a certain manner, and they can produce cancers by injections into test animals of cottonseed oil, olive oil, or tannic acid (a component of many foods). Probably they can do the same thing with other naturally occurring food chemicals. We think that it would unnecessary and undesirable to rule out of the food supply sugar, vegetable oils, or common table beverages simply because, by an extraordinary method of application never encountered at the dining table, it is possible to induce cancer by injecting the substances into the muscles of test animals.

Further, there is no more reason to single out cancer production for specific mention in the legislation than to single out production of high blood pressure, destruction of blood-forming elements of the body, production of nephritis or diabetes, or many other serious disorders. All of these things are of extreme importance and all of them would be covered under the Department-sponsored bill, H. R. 6747. We believe that H. R. 6747 will prohibit the addition of any chemical additive to the food supply until there is adequate assurance acceptable to competent scientists that it will not produce cancer or any other disorder in man under the conditions of use proposed.

2. H. R. 7798, while tending to clarify certain questions as to the scope of coverage of the bill raised under item 4 of our report on H. R. 4014, still leaves some uncertainty in this respect. For example,, it does not state specifically that changes porduced by a chemical additive in food itself (as contrasted with changes in the chemical additive) could be considered in evaluating safety. Such changes do occur and should be considered before any proposed use of an additive is approved.

For the reasons stated above and the additional reasons given in our report on H. R. 4014 and H. R. 4432, we do not favor the enactment of H .R. 7798. Rather, we recommend the enactment of the bill submitted to the Congress by this Department, H. R. 6747.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

DEPARTMENT OF AGRICULTURE,
Washington, D. C., July 15, 1957.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR CONGRESSMAN HARRIS: This is in reply to your request of June 4, 1957, for a report on H. R. 7798, a bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act so as to provide for the safety of chemical additives in food.

The Department has no objection to the enactment of the bill, insofar as it relates to the activities of this Department, provided it is amended as indicated herein. We are not in a position to comment on the effects of the bill on the Department of Health, Education, and Welfare.

The bill defines "chemical additive" as any substance which (1) is intended for use in food or in a collateral way, for example, packaging materials, if such use is likely to result in the contamination of food; and (2) is not generally recognized among experts as having been adequately tested to show either that it is not poisonous or deleterious, or that it is safe for the intended use. However, the definition excludes pesticide chemicals used in the production, storage, or transportation of raw agricultural commodities. The bill provides that any person may file with the Secretary of Health, Education, and Welfare an application containing scientific data for the purpose of establishing that a proposed chemical additive is not a poisonous or deleterious substance, or if it is, that it is safe and is required for its intended use, and that the intended use

of the chemical additive will serve a purpose which will be useful to the consuming public. Within a specified period after the filing of the application, the said Secretary is required to issue an order approving the application or refusing to approve the application. Provision is made for review of the finding in the event the application is denied. The said Secretary, by regulation, shall require the payment of such fees for the performance of the Secretary's functions under this statute as will in the aggregate, in his judgment, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for such function. The legislation is to take effect 6 months after the date of its enactment.

The definition of "chemical additive" should exempt any substance approved prior to the enactment of the bill pursuant to the provisions of the Meat Inspection Act of March 4, 1907, as amended and extended (34 Stat. 1260, as amended and extended; 21 U. S. C. 71 et seq.). In addition, in order that it may be made clear that this bill is not intended to have any amendatory effect upon section 902 (b) of the Federal, Food, Drug and Cosmetic Act (21 U. S. C. 392), an additional provision should be added to the bill reading as follows:

"Nothing in this act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, as amended and extended (34 Stat. 1260, as amended and extended; 21 U. S. C. 71 et seq.)."

Proposed section 409 (a) of H. R. 7798 provides that no person shall introduce or deliver for introduction into interstate commerce any chemical additive, unless the use of such chemical additive has been approved pursuant to this section. From the enforcement standpoint it is evident that occasionally both this Department and the Department of Health, Education, and Welfare might conduct examination of a chemical which would be subject to this bill and to the Federal Insecticide, Fungicide and Rodenticide Act. This would not appear to create any particular difficulty because the investigations would not be parallel. The investigation made by the Department of Health, Education, and Welfare would cover the food uses of the additive and the investigation made by this Department would cover such other uses as would be subject to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.

In dealing with a product that would be both a chemical additive and an economic poison, this Department would not accept for registration purposes directions for use which are likely to result in the product becoming a part of food until the Department of Health, Education, and Welfare has approved the use of such product in or on food. Where an economic poison, presently registered under the Federal Insecticide, Fungicide and Rodenticide Act is deemed to be a chemical additive under this bill, primary jurisdiction over the food uses of such product will be in the Department of Health, Education, and Welfare.

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

TRUE D. MORSE, *Acting Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, July 24, 1957.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter responds to your request for a report on H. R. 8112, a bill to protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of food additives which have not been adequately tested to establish their safety.

This bill is intended to assure the safety of food that has been treated or exposed to food additives such as chemical additives. Part of it is similar to H. R. 6747, which was sponsored by this Department, but in part it differs materially from the latter bill.

H. R. 8112 subdivides food additives into two groups. The one group is defined as "any ingredient intentionally added to food and becoming a component part of food for the purpose of imparting a desired quality to the food" if it is not generally recognized by qualified experts as safe. Additionally, there is a group of "incidental food additive" which is defined as any substance intended for use in manufacturing, packing, processing, preparing, treating, packaging, or

transporting food which foreseeably results, in the course of good manufacturing practice, in its getting into the food.

It is not clear why there should be the distinction between these two types of additives. Whether an additive becomes a component part of the food for the purpose of imparting a desired quality to it or whether it foreseeably becomes such a component as an incident to its use for some other purpose, it should still go through safety-clearance procedures that are adequate to show that the residues remaining do not constitute a hazard to the public health. We believe that it is undesirable to establish the 2 different groups of additives and to establish, as discussed later in this letter, 2 distinctly different procedures for permitting their use in food.

The procedure suggested in the proposed section 410 of the Food, Drug and Cosmetic Act for clearing incidental food additives would not in our opinion adequately safeguard the public health. It provides that any person may file with the Secretary of the Department an application with respect to the use of any incidental food additive. It requires such application to bear a full report of investigations which have been made to show whether or not much incidental food additive migrates into food in a quantity which is toxicologically significant from the standpoint of the protection of public health. It does not specifically state that the application shall contain adequate pharmacological data to permit the Department to determine whether the quantity of an incidental additive remaining is toxicologically significant; this is significant because such a specific requirement is incorporated in the proposed section 409 for food additives.

The proposed section 410 does not require any information about changes that may be induced in food or in its nutritional quality by the incidental additive. This is particularly significant when we consider that the proposed definition of the term "incidental food additive" (the suggested new sec. 201 (t) (1)) includes any radioactive material intended for such use (food use) or as a source for the irradiation of food. The irradiation of food induces material changes. It is not known whether these changes constitute a hazard to the public health, and under the bill as proposed there is no requirement that the manufacturer who irradiates his food should determine in advance of marketing it whether or not it is a hazard. The very complex problems of possible carcinogenicity of irradiated foods or of adverse effects upon reproduction would not have to be answered under this bill by the user of the irradiation process.

Further, the proposed section 410 of the Food, Drug and Cosmetic Act provides that the application, with respect to an incidental food additive, shall be effective on the 90th day after its filing unless prior to such day the Secretary issues an order refusing to permit the application to become effective. If the Secretary does issue such an order of refusal, it must be supported by a statement of reasonable grounds showing that use of such incidental food additive creates a probable risk of injury to public health. What this does is to place the burden of establishing the safety of the incidental additive upon the Government. If the Secretary did not have sufficient information about a proposed additive to determine whether it would create a probable risk of injury, he would have to allow the application to become effective even though its safety had not been established. If he had the facilities to make appropriate scientific tests on the proposed additive, the 90 days ordinarily would be too short for the work that is needed. This represents no improvement over the present law.

Further, it actually represents a regression in law enforcement. At present, under section 406 (a) of the Food, Drug and Cosmetic Act, the Secretary is authorized to limit the poisonous or deleterious substances required in the production of food to such extent as he finds it necessary for the protection of public health. But the proposed section 410 of the act would permit the Secretary to exclude a poisonous or deleterious substance only if he can show that its use would create a probable risk of injury to the public health. It is our view that in any case of doubt the question should be resolved in favor of the consuming public and the additive should not be permitted until it is established beyond a reasonable doubt that there is no hazard from the use of the new material.

The safety standard set up in H. R. 8112 with respect to the other group of additives, the "food additives," likewise is weak in that it provides for the issuance of a regulation permitting a food additive, if its proposed use will be without "reasonable probability of hazard to the health of man or other animals." The comments made above apply with equal force here. In our view, the question to be determined should be, not whether it is reasonably probable that an additive is safe, but whether it is established beyond a reasonable doubt that the additive

is safe. Adequate protection of the public health would appear to require the latter approach.

The proposed section 409 (b) (2) (D) provides that a petition for a regulation permitting a food additive to be used shall contain a description of practicable methods for quantitative determination of such additive and, "to the extent known," its breakdown or reaction products, in or on food referred to in the petition. Many chemical additives are changed by the complex processes of food manufacture into other chemical entities, breakdown, or reaction products, before the food is consumed. These breakdown or reaction products may have effects on the human body that are different from the effects of the original chemical. It would appear necessary for protection of the public health for the person who proposes to use an additive not only to investigate those breakdown or reaction products that are known but also to make a conscious effort to determine what reaction or breakdown products may occur that might be a hazard and to investigate their toxicity.

H. R. 8112 would permit a poisonous or deleterious substance to be added to food solely on a showing of safety and without a showing of functional value or usefulness to the consumer. Because it is impossible to prove the absolute safety of such a chemical to all people under all possible conditions of use, we think it would be proper to permit a poisonous or deleterious substance in amounts judged as safe, only upon a showing that it would have functional value, i. e., would be useful to the manufacturer and the consumer.

There are other respects in which the bill we believe would require revision, but because of the problems mentioned above we have not attempted to discuss them in detail.

We therefore recommend against enactment of H. R. 8112. H. R. 6747, the chemical-additives bill sponsored by this Department, does not have the loopholes that are apparent in H. R. 8112. We recommend enactment of H. R. 6747 in lieu of H. R. 8112.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

M. B. FOLSOM, *Secretary.*

Mr. WILLIAMS. Before hearing the witness scheduled for today, I wish to make a few remarks about these hearings in general and to say a few words about the bills pending before us.

Before I do that, though, I would like to welcome the chairman of our full committee, the Honorable Oren Harris, who is an ex-officio member of this subcommittee. We are delighted to have him sit with us in these hearings this morning.

During the 2d session of the 84th Congress, the Subcommittee on Health and Science, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives.

The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the procedures to be followed in determining the safety of chemical additives.

This disagreement failed to be resolved, and consequently no chemical additive legislation was enacted during the last Congress.

I would like to call to the attention of the witnesses who will testify before the subcommittee in these hearings that, of the 11 members of the subcommittee, only 3 members served on the Subcommittee on Health and Science during the last Congress.

I think I can speak for the three members who sat through the hearings last year, that they may find a little "refresher course" desirable before taking up these bills in executive session. For eight of our subcommittee members, including myself, however, the problems with which these bills deal will be novel ones.

I would like the witnesses to bear this in mind because they may erroneously assume that the members of the subcommittee are already fully familiar with the background and the details of this legislation.

Ten years have passed since the House of Representatives, during the 81st Congress, created a select committee, under the chairmanship of Congressman Delaney, to investigate the use of chemicals in food and cosmetics. The select committee was continued during the 82d Congress, and great credit is due to the chairman and the members of the select committee for the thorough hearings and the extensive report which was filed by that committee.

During the subsequent Congresses, numerous bills have been introduced dealing with the subject of chemical additives. As I have mentioned already, we have pending before us eight different bills on chemical additives.

The first bill, H. R. 366, by our colleague on the committee, Mr. O'Hara, of Minnesota, is similar to the last of the chemical-additive bills which Mr. O'Hara introduced during the 84th Congress and on which hearings were held during that Congress.

H. R. 6747, introduced by Mr. Harris, the chairman of the Committee on Interstate and Foreign Commerce, was introduced at the request of the Department of Health, Education, and Welfare, and it might, therefore, be referred to as the "administration bill." That is H. R. 6747. During the 84th Congress, no administration-sponsored bill was introduced.

H. R. 7700, introduced by Mr. Fulton, is similar to two identical bills introduced by Congressman Delaney, H. R. 7798, and Congresswoman Sullivan, H. R. 7938.

I am advised that H. R. 7798 and H. R. 7938 have superseded two other bills, H. R. 4014 and H. R. 4432, respectively, previously introduced by these same sponsors.

Next we have two identical bills, H. R. 8390 and H. R. 8629, introduced by Mr. Harris and Mr. Wolverton, respectively. I have been given to understand that these bills were introduced at the request of the National Canners Association.

Finally, we have H. R. 8112, introduced by Congressman Miller of Nebraska, who also introduced a bill on this subject during the 84th Congress.

Although, as I have mentioned, some of these bills are identical, the subcommittee has a difficult assignment in trying to appreciate and follow the differences between these bills. In order to make the task of the subcommittee easier, I have directed the staff to attempt to prepare a comparison of these bills, highlighting the differences between them. The staff comparison will be made a part of the record at this point.

I would like to inquire if all members have received a copy of this.

(The document referred to is as follows:)

95208—58——4

Principal features of chemical additives (or food additives) bills to amend the Federal Food, Drug, and Cosmetic Act

SCOPE OF THE BILLS

	H. R. 366, O'Hara	H. R. 6747, Harris	H. R. 7700, Fulton	H. R. 7798, Delaney; H. R. 7938, Sullivan (which supersede H. R. 4014, Delaney; and H. R. 4432, Sullivan)	H. R. 8390, Harris; H. R. 8629, Wolverton	H. R. 8112, Miller
Do the bills differ in the substances they consider to be additives?	Basically the various bills cover the same substances although the substances are referred to differently as follows: New food additives.	Chemical additives.	Chemical additives.	Chemical additives.	New food additives.	Food additives and incidental food additives.
What substances are defined as additives?	Substances used or intended to be used in any phase of food handling or preparation or distribution are additives if they become a component of the food and are not generally recognized as safe for the intended use.					The term "food additive" means ingredients that intentionally become a part of food for the purpose of imparting a desired quality to it, if they are not recognized as safe under the conditions of intended use.
	P. 1, line 16: Definition also includes substances that could reasonably be expected to become a component of food.	P. 1, line 8: Definition also includes substances that may become components of food.	P. 1, line 5: Definitions also include substances that are likely to result in contamination of food.	P. 1, line 5.	P. 1, line 8: Definition also includes substances that could reasonably be expected to become a component of food.	P. 1, line 8: The term "incidental food additive" means substances intended for use in any phase of manufacturing, processing, or handling food which results in its getting into food (p. 2, line 25).
Would a chemical used in manufacturing a food container be considered an additive?	Yes, if it becomes or could reasonably be expected* to become a component of food packed in the container, it would be an additive. P. 1, line 6.	P. 1, line 8. *This bill uses "may" instead of "could reasonably be expected to".	P. 1, line 5. *These bills use "likely" instead of "could reasonably be expected to".	P. 1, line 5.	P. 1, line 8.	It would be an incidental food additive (p. 2 line 25).
Would substances that produce chemical changes in food, such as radiation from isotopes, be additives?	No.	Yes, the definition includes substances that indirectly affect the characteristics of food (p. 1, line 8).	It is not clear that the definition includes radiation from isotopes.	Yes, the definitions are broad enough to include radiation from isotopes, as indicated below: Radioactive material is specifically mentioned (p. 1, line 5).	The definition includes substances that affect the characteristics of food (p. 1, line 8).	Radioactive material is specifically mentioned as an incidental food additive (p. 2, line 25).

Are pesticide chemicals additives?	(1) All bills exempt from the definition of additive, pesticide chemicals applied to crops (raw agricultural commodities).					
	P. 2, line 5.	P. 2, line 15.	P. 2, line 1.	P. 2, line 4.	P. 2, line 10.	P. 2, line 9: But the exemption in this bill does not apply to incidental food additives.
	(2) All bills would include as additives, pesticide chemicals applied to processed foods, after processing.					
	P. 1, line 16.	P. 1, line 8.	P. 1, line 5.	P. 1, line 5.	P. 1 line 8.	P. 2, line 25.
Are pesticide chemicals additives? (cont'd)	(3) Pesticides residues that remain in processed foods because the processor used crops bearing legal residues, would be dealt with as follows:					
	The bill does not mention such residues.	The residues are automatically tolerated in the processed food if they do not exceed the tolerance level allowed on the crop, and if they have been removed during processing to the extent possible in good manufacturing practice (p. 3, line 16).	These bills do not mention such residues.		The residues are automatically tolerated in the processed food if they do not exceed the tolerance level allowed on the crop, and if they have been removed during processing to the extent possible in good manufacturing practice. P. 3, line 13	P. 3, line 23: But this bill does not mention such residues that are incidental food additives.
Are chemicals that get into food by accident considered additives?	No. None of the bills is designed to deal with accidental contamination.					The incidental food additive is a substance whose addition to food is foreseeable from its intended use (p. 2, line 25).
Will a substance that is already recognized as safe have to be cleared?	No, a substance that is generally recognized as safe by appropriately qualified experts would not have to go through the clearance procedures.					
	P. 1, line 6	P. 1, line 8	P. 1, line 5	P. 1, line 5	P. 1, line 8	P. 1, line 8: Except that all incidental food additives would have to go through the clearance procedures (p. 15, line 10).
May a substance be judged safe because it has been used in food for a long time?	The bill does not state whether prolonged use in food could be an adequate test for safety.	Yes. A substance shown through prolonged use in food to be safe under the intended conditions of use may be judged safe (p. 1, line 8).	The bills do not state whether prolonged use in food could be an adequate test for safety.			A food additive shown through prolonged use in food to be safe under the intended conditions of use may be judged safe (p. 1, line 8). All incidental food additives would have to go through the safety clearance procedures (p. 15, line 10).

Principal features of chemical additives (or food additives) bills to amend the Federal Food, Drug, and Cosmetic Act—Continued

SCOPE OF THE BILLS

	H. R. 366, O'Hara	H. R. 6747, Harris	H. R. 7700, Fulton	H. R. 7798, Delaney; H. R. 7938, Sullivan (which supersede H. R. 4014, Delaney; and H. R. 4432, Sullivan)	H. R. 8390, Harris; H. R. 8629, Wolverton	H. R. 8112, Miller
Would a substance already approved for use in food have to be cleared?	No. A substance approved under the Food, Drug, and Cosmetic Act or the Meat Inspection Act would be exempt from the definition of an additive. P. 2, line 5.	P. 2, line 15.	Yes. There is no exemption for a substance with this type of approval.		No. A substance approved under the Food, Drug, and Cosmetic Act or the Meat Inspection Act would be exempt from the definition of an additive. P. 2, line 10.	P. 2, line 9: But all incidental food additives would have to be cleared since there is no exemption because of their prior approval.
Would a substance intended for investigational use have to be cleared?	No. A substance intended solely for investigational use by experts shall be exempted from the clearance procedures. P. 8, line 8.	P. 15, line 4.	P. 8, line 8.	P. 8, line 18.	P. 8, line 8.	P. 14, line 22: But there is no provision for exempting an incidental food additive. It would have to be cleared.
Could a substance intended for uses other than investigational be exempted from the safety clearance procedures?	Yes, when such exemption is consistent with the protection of public health. P. 8, line 8.	P. 15, line 4.	No. There is no provision for such an exemption.		Yes, when such exemption is consistent with the protection of public health. P. 8, line 8.	P. 14, line 22: But there is no provision for such exemption for an incidental food additive.

TESTING AND EVALUATION

What information is required to support a request for approval of an additive?	Pertinent information concerning the chemical additive and where available its identity and composition, a statement of the conditions of use proposed, a description of methods available for insuring the identity of the additive, a description of methods for determining the quantity of the additive, reports of investigations made with respect to toxicity, and a sample of the additive if it is requested by the Secretary of Health, Education, and Welfare. P. 5, line 1.	P. 5, line 12.	P. 3, line 8.	P. 3, line 10.	P. 4, line 20.	P. 5, line 20: For an incidental food additive, a full report of investigations to show whether the additive migrates into food in a quantity that is toxicologically significant (p. 15, line 15).

Must information be supplied about an additive's ability to produce cancer?	Yes, the toxicity investigations would include information on cancer, although cancer is not specifically mentioned. P. 5, line 16.	P. 6, line 7.	P. 3, line 14.	Yes, cancer tests are specifically mentioned (p. 3, line 16).	Yes, the toxicity investigations would include information on cancer, although cancer is not specifically mentioned. P. 5, line 11.	Page 6, line 14; and p. 15, line 15.
Is safety the only factor to be considered before an additive is approved?	Yes.	If the additive is not poisonous or deleterious, safety is the only factor considered. If it is poisonous or deleterious, the Secretary must also consider whether the proposed use has functional value, and applicant must submit data bearing on functional value (p. 8, line 6).	The Secretary must also consider whether the proposed use is useful to the consuming public; and if the additive is poisonous or deleterious he must determine whether the additive is required for its intended use. The applicant must submit relevant data on these matters. P. 4, line 4.	P. 4, line 6.	Yes.	Yes.
In determining whether an additive is safe for use on 1 food, may the Secretary consider the presence of toxic materials on other foods?	Apparently not. He may consider only the food in or on which the additive is used (p. 2, line 16).	Yes; he may consider the presence of toxic materials on other foods. The language permitting this differs as follows: He may take into account any chemically or pharmacologically related substances in the diet where relevant (p. 9, line 1).	He shall take into account the other ways in which the consumer may be affected by the same substance or other substances. Page 5, line 10.	P. 5, line 14.	He may consider all relevant safety factors (p. 5, line 16).	In the case of food additives he may consider any substance in the diet where relevant because of its use in or on foods (p. 8, line 21). The bill does not contain a comparable provision with respect to incidental food additives.
When may an additive be considered safe?	When it is reasonably probable that it will not render food injurious to health (p. 2, line 16; and p. 5, line 21).	When it is safe. When it will be without hazard to health (p. 8, line 6).	The language of the bills varies as follows: If it is not poisonous or deleterious, or if it is, when the use is safe: P. 5, line 10.	P. 5, line 12: Additionally, no additive may be approved if it produces cancer.	When it is safe (p. 5, line 16).	When it will be without reasonable probability of hazard to health (p. 8, line 5). Also an incidental food additive is considered safe unless the Secretary makes a statement that the use creates a probable risk of injury to public health (p. 15, line 22).
After approval, may everyone use an additive?	No. Only the person who submits test data is given the approval (p. 6, line 9).	Yes, approval is made generally known by regulation (p. 6, line 20).	No. Only the person who submits test data is given the approval. P. 4, line 4.	P. 4, line 6.	P. 6, line 4.	Yes. Approval is made generally known by regulation for a food additive (p. 12, line 6). For an incidental food additive only the person who submits test data gets the approval (p. 15, line 22).

Principal features of chemical additives (or food additives) bills to amend the Federal Food, Drug, and Cosmetic Act—Continued

TESTING AND EVALUATION—Continued

	H. R. 366, O'Hara	H. R. 6747, Harris	H. R. 7700, Fulton	H. R. 7798, Delaney; H. R. 7938, Sullivan (which supersede H. R. 4014, Delaney; and H. R. 4432, Sullivan)	H. R. 8390, Harris; H. R. 8629, Wolverton	H. R. 8112, Miller
Does the bill provide for an advisory committee of experts?	No.	Yes (p. 10, line 4).	Yes (p. 4, line 15).	Yes (p. 4, line 17).	No.	For food additives, yes (p. 9, line 21). For incidental food additives, no.
Does the bill provide for a public hearing?	No.	Yes (p. 12, line 22).	Yes (p. 5, line 15).	Yes (p. 5, line 23).	No.	For food additives, yes (p. 12, line 15). For incidental food additives, no.
What type of judicial review does the bill provide for?	Action in a district court for a declaratory judgment (p. 7, line 3).	Review of an order in the circuit court of appeals (p. 14, line 12).	Review of an order in a district court. P. 7, line 20.	P. 8, line 5.	Action in a district court for an injunction (p. 7, line 5).	Review of an order in the circuit court of appeals (p. 14, line 5 and p. 16, line 2).
Does the bill permit an additive to be used in food despite an adverse ruling by the Secretary?	The additive may be used after 60 days prior notice to the Secretary, unless the Secretary institutes an action for declaratory judgment and so notifies the defendant (p. 7, line 16).	No.	No.	No.	The additive may be used after 90 days prior notice to the Secretary, unless injunction proceedings are instituted by the Secretary, and a restraining order or temporary restraining order is issued by the court (p. 6, line 19; p. 7, line 5).	No.
If an additive is used in this way, what can the Secretary do?	Sue for a declaratory judgment, or after shipment institute seizure, injunction and criminal proceedings (p. 7, line 3 and p. 3, line 15).	Institute seizure, injunction and criminal proceedings: P. 3, line 14.	P. 2, line 20.	P. 2, line 22.	Sue for an injunction, and/or institute seizure and criminal proceedings p. 7, line 5).	Institute seizure, injunction and criminal proceedings (p. 3, line 10 and p. 15, line 10).
What would the Secretary have to prove in court in case he took such action?	That the article had not been adequately tested (p. 7, line 16 to p. 8, line 7).	That no order or regulation had been issued to authorize the use. P. 4, line 13.	P. 3, line 4.	P. 3, line 6.	That the article had not been adequately tested. P. 7, line 5.	That no order or regulation had been issued to authorize the use (p. 4, line 20 and p. 15, line 10).

MISCELLANEOUS

How long would the Secretary have to act on a request for approval of an additive?	90 days. The time could be extended by mutual agreement (p. 6, line 3).	90 days. The Secretary could extend the time to 180 days (p. 7, line 20).	90 days (p. 4, line 4).	90 days (p. 4, line 6).	120 days. The time could be extended by mutual agreement (p. 5, line 16).	90 days. For a food additive, the Secretary could extend the time to 180 days (p. 7, line 21, and p. 15, line 22).
Who bears the cost of the clearance procedure?	The Government. P. 9, line 17.	But the person who asks for an advisory committee would pay its cost (p. 11, line 23).	The person who requests approval of the additive. P. 8, line 13.	P. 8, line 23.	The Government. P. 8, line 17.	But the person who asks for an advisory committee would pay its cost (p. 11, line 16, and p. 19, line 1).
Would the Secretary be required to publish a list of additive uses that are already considered safe?	Yes; 6 months prior to the effective date of the bill (p. 8, line 17).	There is no requirement in these bills for such a list.				
When would the law become fully effective?	1 year after enactment (p. 9, line 21).	For new additive uses not employed immediately prior to enactment, 180 days after enactment (p. 15, line 15). For additive uses employed immediately prior to enactment: A. Upon final establishment of a regulation or denial of a petition for a regulation, or B. If earlier: 1 year after enactment with provision for an additional year under appropriate circumstances (p. 16, line 5).	6 months after enactment. P. 8, line 19.	P. 9, line 4.	Upon enactment (no other provision in bill).	For food additive uses not employed immediately rior to enactment, 180 days after enactment (p. 17, line 10). For food additive uses employed immediately prior to enactment: A. Upon final establishment of a regulation or denial of a petition for a regulation, or B. If earlier: 1 year after enactment with provision for an additional year appropriate circumstances (p. 18, line 4). For incidental food additives, 180 days after enactment (p. 17, line 10).

Mr. WILLIAMS. I think that the complexity of the subject of chemical additives and the difficulties which ensue from having so many bills pending before the subcommittee present a great challenge to each of the witnesses to explain to the members of the subcommittee why, in his opinion, the bill he favors is preferable to the other bills. I hope that the witnesses will be mindful, throughout the hearings, of the difficulties under which the subcommittee is laboring in this respect.

I realize that the field of chemical additives is complex and that the legal problems involved in this legislation are important. However, it seems to me that a 10-year period is a sufficiently long incubation period even for difficult legislation.

It is my hope that the 85th Congress will produce chemical-additive legislation which is in the public interest and which will satisfy interested groups in most respects, and I pledge the best efforts of this subcommittee toward this objective.

At this point, I would like to welcome also the ranking minority member of our full Committee on Interstate and Foreign Commerce, Mr. Wolverton, of New Jersey. We are delighted to have you.

Our witness this morning is Charles Wesley Dunn, one of the deans in the field of food and drug legislation and administration. Mr. Dunn will testify on behalf of the Grocery Manufacturers of America.

Mr. Dunn, the committee will be delighted to hear from you. Do you have a prepared statement?

STATEMENT OF CHARLES WESLEY DUNN, GENERAL COUNSEL, GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. DUNN. Yes.

Mr. Chairman, Chairman Harris, Mr. Wolverton, and members of the subcommittee, I make this statement for the Grocery Manufacturers of America, Inc., located at 205 East 42d Street in New York City, of which I have been general counsel almost since its organization in 1912.

It is a national association of food and other grocery manufacturers, and its membership list is filed with the committee at this time.

(The list referred to is as follows:)

LIST OF GROCERY MANUFACTURERS OF AMERICA MEMBER-COMPANIES AND OFFICIAL REPRESENTATIVES

Aborn's Coffee Corp., 371 Greenwich Street, New York, N. Y.
Ac'cent-International, division of International Minerals & Chemicals Corp., 20 North Wacker Drive, Chicago, Ill., T. W. Leary, retail sales manager
Act-O-Products Co., 332 Canal Street, New York 13, N. Y., Samuel A. Wander, president
Alabama Flour Mills Co., Decatur, Ala., Albert Johnson, manager
Alaga Syrup Co., Montgomery, Ala., C. H. Williams, Jr., vice president—sales
American Home Foods, Inc., division of American Home Products Corp., 22 East 40th Street, eNw York 16, N. Y., Walter Silbersack, president
American Kitchen Products Co., 812 Jersey Avenue, Jersey City, N. J., R. G. Janover, president
American Maize-Products Co., 250 Park Avenue, New York 17, N. Y., Theodore Sander, Jr., president
American Pop Corn Co., Sioux City 6, Iowa, Howard C. Smith, president
Anchor Hocking Glass Corp., 415 Madison Avenue, New York 17, N. Y., Richard N. DeMerell, vice president

Anderson, Clayton & Co., foods division, Gibralter Life Building, Post Office Box 35, Dallas 21, Tex., Claude T. Fugua, Jr., president
Angostura-Wuppermann Corp., The, 157 Chambers Street, New York 7, N. Y., Douglas Bradley, president
Armour & Co., Union Stock Yards, Chicago 9, Ill., Walter S. Shafer, vice president
Armstrong Packing Co., Fort Worth, Tex.
Arnold Bakers, Inc., 49 Westchester Avenue, Port Chester, N. Y., J. Dudley Calhoun, vice president
Atlantic gelation division, General Foods Corp., Woburn, Mass.
Atmore & Son, Inc., 110 Tasker Street, Philadelphia 48, Pa.
Austex Foods, Inc., Post Office Box 17, Austin, Tex., Fred W. Catterall, Jr., president
Babbitt, Inc., B. T., 625 Madison Avenue, New York 22, N. Y., Ward F. Parker, vice president and director of marketing
Baker-Gaines division, General Foods Corp., 250 North Street, White Plains, N. Y.
Baker Extract Co., 1 Extract Place, Springfield, Mass., Francis C. Oakley, president
Ball Bros. Co., Box 729 Muncie, Ind., John W. Fisher, vice president, sales
Ball & Co., F. M., Oakland, Calif.
Basic Vegetable Products, Inc., 315 Montgomery Street, San Francisco 4, Calif., Jaquelin H. Hume, vice president
Beatrice Foods Co., 120 South La Salle Street, Chicago 3, Ill., William G Karnes, president
Bedford Products, Inc., 70 West Sixth Street, Dunkirk, N. Y., B. H Bedford, president
Beech-Nut Life Savers, Inc., Canajoharie, N. Y., John A. Grammer, vice president
Bell Co., William G., 189 State Street, Boston, Mass.
Belle Meade Biscuit Co., 627 19th Avenue North, Nashville, Tenn., V. G. Mehser, president
Ben-Hur Products, Inc., division of McCormick & Co., 800 Traction Avenue, Los Angeles 13, Calif.
Benson & Hedges Co., 100 Park Avenue, New York 17, N. Y.
Best Foods, Inc., The, 1 East 43d Street, New York 17, N. Y., L. G. Blumenschine, president
Birds-Eye division, General Foods Corp., 250 North Street, White Plains, N. Y.
Bireley's division, General Foods Corp., Hollywood, Calif.
Black Co., James H., 308 West Washington Street, Chicago 6, Ill., James H. Black, president
Blumenthal Bros. Chocolate Co., Margaret and James Streets, Philadelphia 37, Pa., Joseph Blumenthal, treasurer
Bon Ami Co., 17 Battery Place, New York 4, N. Y., Harry S. Adams, executive vice president
Borden Co., The, 350 Madison Avenue, New York 17, N. Y., W. H. Gurley, vice president
Bordo Products Co., 2835 Sheffield Avenue, Chicago 14, Ill., A. L. Koch, vice president, charge of sales
Bowman Biscuit Co., The, Box 5450, Terminal Annex, Denver 17, Colo., J. C. Bowman, president
Bowey's, Inc., 771 Bedford Avenue, Brooklyn 5, N. Y., Charles F. Bowey, executive vice president
Boyle-Midway Inc., 220 Seventh Street, Canton 2, Ohio
Brach & Sons, E. J., 4600 West Kinzie Street, Chicago 44, Ill., Edwin O. Blomquist, vice president
Brick & Son, Edgar, Crosswicks, N. Y., Arthur R. Brick
Brillo Manufacturing Co., Inc., 60 John Street, Brooklyn 1, N. Y., Milton B. Loeb, president
Brooklyn Products Co., Brooklyn, Mich.
Brooks Foods, Inc., Route 40, Collinsville, Ill., Gerhart S. Suppeger, Jr., president
Brown & Williamson Tobacco Corp., 1600 West Hill Street, Louisville 1, Ky., Addison Yeaman, general counsel
Burnett Co., Joseph, Elkhart, Ind.
Burnham & Morrill Co., 45 Water Street, Box 1871, Portland, Maine, E. R. Elwell, vice president
Burton & Co., Inc., W., foot of Joralemon Street, Brooklyn 2, N. Y.
Burton-Morrow Co., Inc., foot of Joralemon Street, Brooklyn 2, N. Y.
Cain Co., John E., 678 Massachusetts Avenue, Cambridge 39, Mass. Robert H. Cain

California Packing Corp., 215 Fremont Street, San Francisco 19, Calif., Roy G. Lucks, president
Campbell Sales Co., 100 Market Street, Camden, N. J., William B. Nixon, president
Canada Dry Ginger Ale, Inc., 100 Park Avenue, New York 17, N. Y. Allen W. Waltz, assistant to the president
Cannon & Son, Inc., H. P., Bridgeville, Del. H. P. Cannon II, president
Cantrell & Cochrane Corp., 270 Park Avenue, New York 17, N. Y., Walter S. Mack, Jr., president
Carnation Co., 5045 Wilshire Boulevard, Los Angeles 36, Calif., Ralph R. Brubaker, vice president
Certified Extracts, Inc., 811 East 139th Street, Bronx 54, N. Y.
Charmin Paper Products Co., Green Bay, Wis.
Chef Boy-Ar-Dee Quality Foods Co., Milton, Pa.
Chemicals, Inc., San Francisco, Calif.
Chesebrough-Pond's, Inc., 485 Lexington Avenue, New York 17, N. Y., E. D. Lane, vice president and sales manager
Chicago Carton Co., 4200 South Crawford Avenue, Chicago, Ill., E. W. Johnson, vice president
Church & Dwight Co., Inc., 70 Pine Street, New York 5, N. Y., Henry M. Minton, president
Cinch Products, Inc., 4540 West Colorado Boulevard, Los Angeles 26, Calif., Jack Taylor, president
Clapp, Inc., Harold H., 370 Lexington Avenue, New York 17, N. Y.
Climalene Co., The, Canton 1, Ohio, R. H. Marriott, vice president
Clorox Chemical Co., 850 42d Avenue, Oakland 1, Calif., W. J. Roth, president
Coca-Cola Co., The, Atlanta, Ga., William E. Robinson, president, 515 Madison Avenue, New York 22, N. Y.
Colgate-Palmolive Co., 300 Park Avenue, New York 22, N. Y.
College Inn Food Products Corp., 4301 South Ashland Avenue, Chicago 9, Ill., Willard Eliel, president
Comet Rice Co., 300 Gulf States Building, Dallas, Tex., Robert B. Holland, Jr., chairman of the board
Connecticut Chemical Research Corp., 706 Bostwich Avenue, Bridgeport, Conn.
Continental Baking Co., Inc., Post Office Box 731 Rye, N. Y., R. Newon Laughlin, president
Cook Chemical Co., Post Office Box 78, Kansas City 41, Mo., James R. Groebe, vice president
Corn Products Refining Co., 17 Battery Place, New York 4, N. Y., William T. Brady, president
Cream of Wheat Corp., The, 730 Stinson Boulevard, Minneapolis 13, Minn., Daniel F. Bull, president
Creamette Co., The, 428 First Street North, Minneapolis, Minn., James T. Williams, Jr., president and treasurer
Crosse & Blackwell Co., The, 6801 Eastern Avenue, Baltimore 24, Md., John T. Menzies, president
Crown Cork & Seal Co., Inc., Eastern Avenue and Kresson Street, Baltimore, Md., S. V. Tuttas, director of sales
Crown Zellerbach Corp., 343 Sansome Street, San Francisco 19, Calif., L. W. Moore
Curtiss Candy Co., 3638 North Broadway, Chicago 13, Ill., Philip B. Schnering, vice president
Dannemiller Coffee Co., 116 39th Street, Brooklyn 32, N. Y., Edward I. Dannemiller, president
Davis Company, R. B., 38 Jackson Street, Hoboken, N. J., B. E. Snyder
Derby Co., H. C., 425–429 Fairmount Avenue, Philadelphia, Pa.
Derby Foods, Inc., 3327 West 47th Place, Chicago, Ill.
Diamond Crystal Salt Co., St. Clair, Mich., Charles F. Moore, president
Dixie Cup Co., Easton, Pa., J. Russell Wood
Dorann Foods, Inc., 2 West Purdy Avenue, Rye, N. Y., R. W. Stanford, vice president
Dow Chemical Co., The, Midland, Mich., W. L. Nelson, sales manager of Saran Wrap
Doxsee Co., Inc., The, foot of Joralemon Street, Brooklyn 2, N. Y.
Drackett Products Co., The, 5020 Spring Grove Avenue, Cincinnati 32, Ohio. Athur H. Boylan, president

Dromedary Co., The, 110 Washington Street, New York 6, N. Y., William F. Redfield, president
Duffy-Mott Co., Inc., 370 Lexington Avenue, New York 17, N. Y., H. E. Meinhold, president
Dunaway Corp., Judson, Dover, N. H., Sam Knox, president
du Pont de Nemours & Co., Inc., E. I., Nemours Building, Wilmington, Del., H. B. Putney, manager, cellulose sponge sales
Durkee Famous Foods, Inc., 82 Corona Avenue, Elmhurst, N. Y., P. D. Hursh, general manager
Durkee-Mower, Inc., Post Office Box 470, 2 Empire Street, East Lynn, Mass., H. Allen Durkee, president
Dwineli-Wright Co., 68 Fargo Street, Boston 5, Mass., Sumner A. Mead, president
Enzo-Jel Co., Ninth at Pennsylvania, Post Office Box 530, Sheboygan, Wis., William E. Hoerres, president
Faultless Starch Co., 1025 West Eighth Street, Kansas City 7, Mo., Gordon T. Beaham, Jr., president and treasurer
Fear & Co., Fred, foot of Joralemon Street, Brooklyn 2, N. Y., Leo Green, president
Felber Biscuit Co., Grant Avenue and McCoy Street, Columbus 3, Ohio, Roy Woerner, president
Filbert, Inc., J. H., 3701 Southwestern Boulevard, Baltimore 29, Md., T. Harvey James, vice president
Flako Products division of the Quaker Oats Co., Post Office Box 1071, New Brunswick, N. J.
Flav-R-Straws, Inc., of New York, 80 West Broad Street, Mount Vernon, N. Y. Raymond E. Gaylord, vice president
Fleischmann's Malting Co., 327 La Salle Street, Chicago, Ill.
Ford Products Co., Inc., Luther, 100 North Seventh Street, Minneapolis 3, Minn., Luther Ford
Foulds Milling Co., West Chester, Pa.
Franco-American Food Co., Camden, N. J.
French Co., The R. T., 1 Mustard Street, Rochester 9, N. Y., J. D. Cockcroft, president
Frenchette Co., Inc., The, 2 Park Avenue, New York 16, N. Y., J. George Spitzer, president
Frigidinner, Inc., 1933 Reed Street, Philadelphia 46, Pa., Thomas R. Sterck, president
Fruit Dispatch Co., Pier 3, North River, New York 6, N. Y., Russell G. Partridge, director of advertising and sales
Fuji Trading Co., The, 441 West Huron Street, Chicago 10, Ill., Y. Miya, secretary
Gebhardt Chili Powder Co., The, 122 South Frio Street, San Antonio, Tex., T. A. Lambert, president
General Baking Co., 420 Lexington Avenue, New York 17, N. Y., Russell J. Hug, president
General Electric Co., large lamp department, Nela Park, East Cleveland 12, Ohio, J. M. Lime, manager, retail sales
General Foods Corp., 250 North Street, White Plains, N. Y., George Hampton, executive vice president
General Mills, Inc., 400 Second Avenue South, Minneapolis 1, Minn., Walter R. Barry, vice president
Gerber Products Co., Fremont, Mich., Dan F. Gerber, president
Gillette Safety Razor Co., Gillette Park, Boston 6, Mass., Robert P. Neuffer
Globe Mills, 907 East Third Street, Los Angeles, Calif.
Good Luck Food Co., Inc., 101 Manhattan Street, Rochester 7, N. Y.
Gordon Foods, Inc., 1075 Sylvan Road SW., Atlanta 10, Ga., P. F. O'Brien, president
Gorton's of Gloucester, 327 Main Street, Gloucester, Mass., W. Welles Sellew, vice president
Grass Noodle Co., Inc., I. J., 6015–127 Wentworth Avenue, Chicago 21, A. I. Grass, president
Green Giant Co., Le Sueur, Minn., W. F. Dietrich, president
Grocery Store Products Co., West Chester, Pa., J. S. Ross, president
Gulden, Inc., Charles, 296 Midland Avenue, Saddle Brook, N. J., Charles Gulden, president
Halferty & Co., Inc., G. P., 512 Colman Building, Seattle, Wash., G. P. Halferty, president

Hawaiian Pineapple Co., Ltd., Fifth and Virginia Streets, San Jose 8, Calif., Hal M. Chase, vice president.
Heinz, Co., H. J., 1062 Progress Street, Pittsburgh 30, Pa., Frank Armour, Jr., vice president
Hekman Biscuit Co., 310 28th Street SE., Grand Rapids 8, Mich.
Help, Inc., 122 West Kinzie Street, Chicago 10, Ill., Peter S. Bezek, president
Hercules Chemical Co., Inc., 332 Canal Street, New York 13, N. Y.
Hershey Chocolate Corp., Hershey, Pa., J. J. Gallagher, chairman of the board
Heublein, Inc., 330 New Park Avenue, Hartford 1, Conn., J. J. Bizik, vice president
Hewitt Soap Co., Dayton, Ohio
Hilex Co., 319 East Kellogg Boulevard, St. Paul 1, Minn., Asa A. Eldredge, president
Hoffman Beverage Co., 400 Grove Street, Newark 6, N. J., George W. Fraser, executive vice president
Holly Products Co., 4726 Loma Vista Avenue, Vernon, Calif.
Hormel & Co., George A., Austin, Minn., R. D. Arney, vice president
Hubinger Co., the, 601 Main Street, Keokuk, Iowa, A. M. Robinson, vice president, charge of sales
Hudson Pulp & Paper Corp., 477 Madison Avenue, New York 22, N. Y., Irwin A. Zuckerman, vice president, charge of sales
Hurff Co., Edgar F., Swedesboro, N. J.
Hygienic Products Co., the, Canton 2, Ohio
Illinois Canning Co., Hoopeston, Ill., L. Ratzesberger, Jr., president.
Jacobs, Inc., Edward H., West Chester, Pa.
Jelke Good Luck Products, 390 Park Avenue, New York 22, N. Y.
Jell-O division, General Foods Corp., 250 North Street, White Plains, N. Y.
Johnson & Son, Inc., S. C., Racine, Wis., R. W. Carlson, general sales manager
"Junket" Brand Foods, Hansen Island, Little Falls, N. Y., A. C. Benjamin, president
Keebler Biscuit Co., G Street and East Hunting Park Avenue, Philadelphia 24, Pa., J. Y. Huber, Jr.
Kellogg Co., Battle Creek, Mich., L. C. Roll, president
Kessler-Gallagher & Burton divisions (Seagram-Distillers Co.), 405 Lexington Avenue, New York 17, N. Y.
Kimberly-Clark Corp., Cellucotton division, 919 North Michigan Avenue, Chicago 11, Ill., C. E. Souders, general sales manager, Neenah, Wis.
Kitchen Bouquet, Inc., West Chester, Pa.
Knouse Foods, Inc., Peach Glen., Pa., M. E. Knouse, president
Knox Gelatine Co., Inc., Charles B., 13 Knox Avenue, Johnstown, N. Y., James E. Knox, chairman of the board
Kraft Foods Co., 500 Peshtigo Court, Chicago 90, Ill., Grel Pound, chairman of the board
LaChoy Food Products, Inc., Archbold, Ohio, Edward M. Muldoon, general manager
LaRosa & Sons, Inc., V., 473 Kent Avenue, Brooklyn 11, N. Y., Vincent S. LaRosa, vice president
Larrowe Mills, Inc., Cohocton, N. Y., Edwin W. Folts, president
Larsen Co., The, 314 North Broadway, Green Bay, Wis., R. E. Lambeau, president
Larus & Bro. Co., Inc., Post Office Drawer 6-S, Richmond 17, Va., William T. Reed, Jr., president
Lea & Perrins, Inc., 241 West Street, New York 13, N. Y., H. J. Dittrich, vice president
Lever Brothers Co., 390 Park Avenue, New York 22, N. Y., Jervis J. Babb, chairman of the board
Libby, McNeill & Libby, Union Stock Yards, Chicago 9, Ill., Charles S. Bridges, president
Lipton, Inc., Thomas J., Hoboken Terminal, Hoboken, N. J., Robert B. Smallwood, chairman of the board
Lorillard Co., Inc., P., 119 West 40th Street, New York 18, N. Y., Lewis Gruber, president
Los Angeles Soap Co., 617 East First Street, Los Angeles 54, Calif., Andrew K. Forthmann, president
Magnus Chemical Co., Inc., South Avenue, Garwood, N. J., W. M. Campbell, president
Maltex Co., Post Office Box 697, Burlington, Vt.

Malt-O-Meal, Co., Foshay Tower, Minneapolis 2, Minn., John Campbell, president
Manchester Biscuit Co., 205–15 Sixth Street, Sioux Falls, S. D., W. C. Brinley, president
Manchester Biscuit Co., 124 North 13th Street, Fargo, N. Dak., A. M. Dargan, president
Mangels Herold Co., Inc., 1414 Key Highway, Baltimore 30, Md., Walter B. Mangels, Jr., president
Manhattan Soap Co., 441 Lexington Avenue, New York 17, N. Y.
Marcal Paper Mills, Inc., River Road, Paterson, N. J., J. J. Schmitt, sales manager
Martinson & Co., Joseph, 190 Franklin Street, New York 13, N. Y., Jerome S. Neuman, president
Mawer-Gulden-Annis, Inc., 87 34th Street, Brooklyn 32, N. Y., Bradley H. Mawer, secretary
Mayer & Co., Oscar, Madison 1, Wis., W. R. Boberschmidt, sales promotion manager
Maxwell House Products Co., 1125 Hudson Street, Hoboken, N. J.
McCormick & Co., Inc., Light and Barre Streets, Baltimore 2, Md., John N. Curlett, president
McIlhenny Co., Inc., Avery Island, La., W. S. McIlhenny, president
McKenzie Milling Co., Quincy, Mich., C. D. McKenzie, president
Mead Johnson & Co., Evansville 21, Ind., Craig Campbell, vice president
Merchants Biscuit Co., 4301–19 North 30th Street, Omaha, Nebr., W. P. Nolan, president
Metal Textile Corp., 647 East First Avenue, Roselle, N. J., Russell B. Kingman, chairman of the board
Milner Products Co., Post Office Box 4465, Fondren Station, Jackson, Miss., Howard S. Cohoon, president
Minute Maid Corp., 488 Madison Avenue, New York 22, N. Y., John Fox, president
Monsanto Chemical Co. (Consumer Products division), 800 North 12th Boulevard, St. Louis 1, Mo., H. H. Balthaser, grocery sales manager
Morgan Cotton Mills, Inc., Laurel Hills, N. C., R. D. Sanders, vice president
Morris, Inc., Philip, 100 Park Avenue, New York 17, N. Y., Ray Jones, vice president
Morrison Co., Inc., 1007–19 Vine Street, Philadelphia 7, Pa., H. S. Frank, president
Morton Salt Co., 120 South La Salle Street, Chicago 3, Ill., Daniel Peterkin, Jr., president
Mueller Co., C. F., 146–184 Baldwin Avenue, Jersey City 6, N. J., C. F. Mueller, executive vice president
Murray Co., The, 155 North Beacon Street, Boston 35, Mass., Fred R. Nye, national sales manager
Myles Salt Co., 1048 Constance Street, New Orleans 9, La.
National Biscuit Co., 425 Park Avenue, New York 22, N. Y., George Coppers, president
National Bread Co., 425 Park Avenue, New York 22, N. Y.
National Cranberry Association, Main Street, Hanson, Mass., Kenneth G. Garside, vice president
National Dairy Products Corp., 260 Madison Avenue, New York 16, N. Y.
National Oats Co., Cedar Rapids, Iowa, James L. Cooper, president
National Selected Products, Inc., 551 Fifth Avenue, New York 17, N. Y., Chester Barth, president
Nehi Corp., Columbus, Ga., F. E. Gorman, vice president
Nestle Co., Inc., 2 William Street, White Plains, N. Y., H. J. Wolflishberg, president
New England Canners, division of H. C. Brill Co., 375 Verona Avenue, Newark, N. J., H. C. Brill, Jr., president
New England Fisheries, foot of Joralemon Street, Brooklyn 2, N. Y.
New York Dugan Bros., Inc., 97–11 222d Street, Queens Village, N. Y., Berkeley Nosworth, general manager
Noma Lites, Inc., 55 West 13th Street, New York 4, N. Y., Nick Lukats, sales manager
Northern Paper Mills (div. of Marathon Corp.), Green Bay, Wis., John B. Kohl, general sales manager
O-Cel-O division (Division of General Mills, Inc.), 1200 Niagara Street, Buffalo 13, N. Y.

Ohio Salt Co., The, Wadsworth, Ohio
Old Dutch Coffee Co., Inc., 80 Front Street, New York 5, N. Y., John McQuade, director of merchandising
Ontario Biscuit Co., 12–20 Watson Street, Buffalo, N. Y., Donald K. Templeton, president
Orford Soap Co., Manchester, Conn.
Owens-Illinois Glass Co., Toledo 1, Ohio, Kent S. Upham, sales manager to the Food Industries division
Paas Dye Co., 60 Shipman Street, Newark 2, N. J., P. B. Townley, president
Pabst Brewing Co., Merchandise Mart Plaza, Chicago 54, Ill., William Dillingham, executive vice president
Pacific Hawaiian Products Co., 336 East Santa Fe Avenue, Fullerton, Calif., Reuben P. Hughes, president
Parsons Ammonia Co., Inc., 19 Rector Street, New York 6, N. Y., Philip Ingham, president
Paulus Bros. Packing Co., Salem, Oreg.
Penick & Ford, Ltd., Inc., 420 Lexington Avenue, New York 17, N. Y., Marion J. Martin, executive vice president
Pennsalt Chemicals Corp., 3 Penn Center Plaza, Philadelphia 2, Pa., Harold A. Fletcher, manager of sales
Pepper Co., Dr., Post Office Box 5086, Dallas 2, Tex., Wesby R. Parker, executive vice president
Pepperidge Farm, Inc., Norwalk, Conn., John J. Brady, national sales manager
Pepsi-Cola Co., 3 West 57th Street, New York 19, N. Y., Alfred N. Steele, chairman of the board
Perkins divisions, General Foods Corp., 7400 South Rockwell Street, Chicago 29, Ill.
Permacel Tape Corp., Post Office Box 671, New Brunswick, N. J., F. D. Clark, consumer sales manager
Personal Products Corp., Milltown, N. J., Robert P. Swan, director, trade relations
Pet Milk Co., 1401 Arcade Building, St. Louis 1, Mo., Jule P. Miller, vice president
Pfeiffer's Food Products, Inc., 2675 Main Street, Buffalo, N. Y., Kaseal W. Peckoff, executive vice president
Phillips Packing Co., Inc., Cambridge, Md., Albanus Phillips, Jr., president
Pillsbury-Ballard division, 912 East Broadway, Louisville 4, Ky.
Pillsbury Mills, Inc., 600 Pillsbury Building, Minneapolis 2, Minn., Paul S. Gerot, president
Planter Nut & Chocolate Co., Wilkes-Barre, Pa., F. A. English, president
Post Cereals division, General Foods Corp., Battle Creek, Mich.
Prescott Co., Inc., J. L., 27 Eighth Avenue, Passaic, N. J., C. E. Prescott, president
Procter & Gamble Distributing Co., the Gwynne Building, Post Office Box 599, Cincinnati 1, Ohio, Mark Upson, vice president, food products division
Prudence Foods, Inc., 188 State Street, Boston 9, Mass., Harry D. Carter, president
Puhl Products Co., The John, 5900 West 51st Street, Chicago 38, Ill., S. H. Kord, president
Pure Food Co., Inc., The, Mamaroneck, N. Y., L. A. Farnan, sales manager
Purex Corp., Ltd., 9300 Rayo Avenue, South Gate, Calif., Craig Davidson, vice president and marketing director
Purity Biscuit Co., 471 West Fifth Street, Salt Lake City, Utah, V. A. Tracy
Quaker Oats Co., The, Merchandise Mart Plaza, Chicago 54, Ill., Donold B. Lourie, president
Quality Biscuit Co., 1512 West Pierce Street, Milwaukee 1, Wis., Fred W. Krause, vice president and general manager
Ralston Purina Co., 835 South Seventh Street, St. Louis 2, Mo., Geoffrey Baker, vice president in charge of grocery products department
Rath Packing Co., The, Waterloo, Iowa, Ned Cone, manager, vacuum cooked meat department
Ravarino & Freschi, Inc., 4651 Shaw Boulevard, St. Louis, Mo., A. Ravarino, president
Red Star Yeast & Products Co., 221 East Buffalo Street, Milwaukee 1, Wis., R. D. L. Wirth, president
Reymer & Brothers, Inc., Post Office Box 508, Pittsburgh 30, Pa., P. B. Grosscup, Jr., president
Reynolds Metals Co., 2500 South Third Street, Louisville, Ky., Clarence F. Manning, vice president
Richmond-Chase Co., Post Office Box 1030, San Jose 8, Calif., E. N. Richmond, president

Ritter Co., P. J., Bridgeton, N. J., William H. Ritter, Jr., president
Rockwood & Co., 88 Washington Avenue, Brooklyn 5, N. Y., H. Russell Burbank, chairman of the board
Royal Baking Powder Co., 595 Madison Avenue, New York 22, N. Y.
Rutherford Food Corp., 416 East Third Street, Kansas City 6, Mo., George Van Voorst, president
Salada Tea Co., Inc., Stuart & Berkeley Streets, Boston 16, Mass., Edgar Pinto, vice president
San Georgio Macaroni, Inc., Lebanon, Pa., R. Guerrisi, president
Sawyer Biscuit Co., Town House Square, 2407–2411 West North Avenue, Melrose Park, Ill., L. P. Reed, president
Schaefer Brewing Co., The F. & M., 430 Kent Avenue, Brooklyn 11, N. Y., John T. Morris, director of marketing
Schilling & Co., A., Second and Folsom Streets, San Francisco, Calif.
Schulze & Burch Biscuit Co., 1133 West 35th Street, Chicago 9, Ill., E. F. Chambless, president
Scott Paper Co., Front and Market Streets, Chester, Pa., Francis W. Plowman, vice president
Scull Co., Inc., Wm. S., Front and Federal Streets, Camden, N. J., R. B. Scull, chairman of the board
Seabrook Farms Co., Seabrook, N. J., C. Courtney Seabrook, vice President
Seven-Up Co., The 1316 Delmar Boulevard, St. Louis 3, Mo., John T. Tabor, assistant to the president
Simoniz Co., 2100 Indiana Avenue, Chicago 16, Ill., Elmer Rich, Jr., president
Skinner Manufacturing Co., 14th and Jackson Streets, Omaha 8, Nebr., John T. Jeffrey, vice president in charge of sales
Slade Co., D. & L., 189 State Street, Boston 9, Mass., N. S. Dillingham, treasurer
S. O. S. Co., The, 6201 West 65th Street, Chicago 38, Ill., George W. Brooks, vice president and general manager
Stahl-Meyer, Inc., 172 East 127th Street, New York 35, N. Y., Frank J. Guthrie, general sales manager
Staley Manufacturing Co., A. E., Decatur 23, Ill., E. K. Scheiter, executive vice president
Standard Brands, Inc., 625 Madison Avenue, New York 22, N. Y., A. R. Fleischmann, vice president
State Brand Creameries, Inc., Mason City, Iowa, Leo Benson, general manager
Stegner Food Products, Inc., 1026 Township Avenue, Cincinnati 25, Ohio, E. J. Stegner, secretary
Stokely-Van Camp, Inc., 941 North Meridian Street, Indianapolis 7, Ind., H. F. Krimendahl, president
Straub & Co., W. F., 5520 Northwest Highway, Chicago 30, Ill., Walter F. Straub, president
Strietmann Biscuit Co., The, Trade Street and Wooster Pike, Mariemont, Cincinnati 27, Ohio, G. H. Strietmann, president
Strohmeyer & Arpe, Co., 139–141 Franklin Street, New York 13, N. Y., W. A. Benz, president
Sunkist Growers, Inc., 616 East Grove Street, Ontario, Calif., Donald R. Thompson, manager, products department
Sunshine Biscuits, Inc., 29–10 Thomson Avenue, Long Island City 1, N. Y., Hanford Main, president
Swift & Co., Union Stock Yards, Chicago 9, Ill., H. E. Wilson, assistant to the president
Taylor-Reed Corp., The, 15 Crescent Street, Glenbrook, Conn., Malcolm P. Taylor, chairman of the board and vice president of sales and advertising
Tetley Tea Co., Inc., 483 Greenwich Street, New York 13, N. Y., Edward C. Parker, president
Texize Chemicals, Inc., Post Office Box 1820, Greenville, S. C., E. H. Kittredge, Jr., vice president
Thatcher Glass Manufacturing Co., Inc., Elmira, N. Y., P. S. Holmquest, vice president
Tidy House Products Co., 604 West Thomas Street, Shenandoah, Iowa, William Church, director of sales
T–N–T Food Products, Inc., Lawrence, Kans., B. A. Barteldes, general manager
Trade Winds Foods, Inc., 75 West Street, New York 6, N. Y.
Tupman Thurlow Co., Inc., The, 155 East 44th Street, New York 17, N. Y., T. Parrott, general sales manager
TV Time Foods, 6570 North Sheridan Road, Chicago 26, Ill., Willard J. Coert, sales manager

Underwood Co., Wm., 85 Walnut Street, Watertown, Mass., G. C. Seybolt
United Biscuit Company of America, 2407–2411 West North Avenue, Melrose Park, Ill., K. F. MacLellan, president
United States Borax & Chemical Corp., 630 Shatto Place, Los Angeles 5, Calif., D. V. Parker, vice president and general manager, Twenty Mule Team Products division
Van Brode Milling Co., Inc., Post Office Box 300, Clinton, Mass., David Brody, president
Van Loan & Co., Inc., 176 Franklin Street, New York 13, N. Y., John Max Weyer, president
Virginia Dare Extract Co., Inc., Bush Terminal No. 10, 882 Third Street, Brooklyn 32, N. Y., L. E. Smith, president.
Wander Co., The, 105 West Adam Street, Chicago 3, Ill., Hart Johnston, president
Washburn Crosby Co., Inc., Chicago, Ill.
Washington Coffee Refining Co., G., 22 East 40th Street, New York 16, N. Y.
Welch Grape Juice Co., The, Westfield, N. Y., Howard F. Nuss, vice president, sales and advertising
Wesson Oil & Snowdrift Co., Inc., 210 Baronne Street, New Orleans 12, La., A. Q. Petersen, chairman of the board
Westinghouse Electric Co., Lamp division, Bloomfield, N. J., H. J. Hanbury, manager, photographic lamp sales
Weston Biscuit Co., Inc., 2 Brighton Avenue, Passaic, N. J., J. C. McMullen, president
Wheatena Corp., The, Wheatenaville, Rahway, N. J., George B. Wendell, president
Wilbert Products Co., Inc., 805 East 139th Street, New York 54, N. Y., William A. Dolan, president
Wood & Selick Sweetened Coconut Co., Inc., 19 Rector Street, New York 6, N. Y., J. S. Calvert, president
Young, Inc., W. T., Lexington, Ky.
Zerega's Sons, Inc., A., Fairlawn, N. J., John P. Zerega, Jr.
Zinsmaster Hol-Ry Co., 2415 West Superior Street, Duluth, Minn., H. W. Zinsmaster, president

Mr. DUNN. This association which I represent has the distinction of being the only general national organization of food manufacturers, which includes leading food manufacturers of every kind throughout the country, and whose products are more or less used in every home. Some association members more or less dissent from this statement; and each association member has a reserved right to make an individual statement to this committee.

This statement also expresses my own view, as a lawyer who has specialized in the food and drug law for over 45 years, or nearly as long as the life of our national law here. While thus speaking for myself, it may be added that I now hold the following related offices: Chairman of the respective divisions on this law in the American and New York State Bar Associations; editor of the Journal on this law; and president of the Food Law Institute, a public organization established by major food manufacturers to develop a better general knowledge of this law through research studies of it and law school instruction in it, and by other educational means.

Moreover, I have professorial charge of the national graduate program on this law at the New York University School of Law; and I was a member of the Citizens Advisory Committee appointed by the Secretary of Health, Education, and Welfare to study the administration of the Federal Food, Drug and Cosmetic Act, which made a basic report in 1955, House Document No. 227, 84th Congress, 1st session.

These prefatory remarks should also record our appreciation to the committee and Chairman Harris for receiving this statement before I leave for Europe on July 17, to chair an international conference.

on July 26 in London, on the control of chemical additives in food, which is the question now before this committee.

That conference will be addressed by the highest food-law officials in the United States, Canada, and Great Britain, and I may say also in western continental Europe; and it was organized by the Food Law Institute, of which I am president, which also organized the national meeting last year, 1956, to commemorate the 50th anniversary of our national pure food and drug law.

These hearings deal with an amendment of the Federal Food, Drug and Cosmetic Act—called the FDC Act—to assure the safe use of "chemical additives" in food. This amendment is best discussed, in our view, through an examination of H. R. 6747, introduced by Chairman Harris. For it is the administration bill for such an amendment, which was drawn by the Food and Drug Administration—called the FDA—and which is recommended by the Secretary of Health, Education, and Welfare, who well administers this act through the FDA.

Its Senate counterpart is S. 1895, introduced by Chairman Hill, of the Senate Committee on Labor and Public Welfare, with Senators Smith of New Jersey, and Sparkman.

Other House bills have been introduced for a similar amendment, as the chairman has pointed out, of the FDC Act, which are cited in a footnote. These bills are H. R. 366 (O'Hara), H. R. 4041 (Delaney), H. R. 4432 (Sullivan), H. R. 7700 (Fulton), H. R. 7798 (Delaney), H. R. 7938 (Sullivan), H. R. 8112 (Miller), and H. R. 8390 (Harris). Analogous cosmetic amendments are proposed by H. R. 4015 (Delaney) and H. R. 4431 (Sullivan); and the organized cosmetic industry has reportedly drafted its own amendment bill, and they invite due comparative review.

This is especially so with respect to H. R. 366 (O'Hara) and H. R. 8390 (Harris), because they were responsibly developed in the food and chemical industries; and it may be noted that I joined in their original preparation.

The CHAIRMAN. Mr. Chairman, if I may be permitted an interruption.

Mr. Wolverton was not here at the time, I believe, that I introduced H. R. 8390——

Mr. DUNN. Yes.

The CHAIRMAN. But did later introduce an identical bill. His bill is to be included and considered along with the rest of them.

Mr. DUNN. That is true. I have been in Vermont on vacation, so, Mr. Wolverton, I was not informed about your introduction of the parallel bill to H. R. 8390.

H. R. 8112, by Mr. Miller, also invites special attention, since it further regulates incidental food additives, which, for example, migrate from food containers; but it otherwise follows the general pattern of H. R. 6747, the Administration bill, with some modifications.

Because it is a responsible national association of food manufacturers, the Grocery Manufacturers of America, Inc., necessarily approves the public purpose of the amendment proposed by H. R. 6747, the Administration bill. For this amendment is designed to require that substances deliberately—the FDC Act now similarly requires the pretesting of pesticide chemicals which may accidentally contaminate natural food, as later noted—added to food shall be ade-

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quately tested through appropriate scientific procedures to establish that they are actually safe for use under the conditions of their intended use, if and to the extent such precautionary action is scientifically indicated to protect the public health.

The responsibility of complying with this requirement would primarily fall on the seller of a regulated food additive in interstate commerce. But the final responsibility of doing so would reside in the manufacturer of a food containing the additive, who ships it in such commerce and thus becomes legally accountable for its safety under the FDC Act. He might, however, obtain a guaranty from his supplier of the additive that its use will not violate this amended act, which would be a defense against his criminal prosecution thereunder for using it. Hence, we suggest that this amendment be revised to recognize that guaranty protection, which is done in the similar pesticide chemical amendment.

Hence, this amendment is not confined, as its terms imply, to food chemical additives in an industrial sense, although it mainly regulates them; and its requirement actually broadly reaches all food additives as thus provided.

Such requirement is basically a pretesting one for new food additives, but it also importantly regulates old food additives; and it expresses a true food-law philosophy that the safety of a food shall be determined before it is sold and consumed.

Whereas the FDC Act now prohibits a food that is unsafe, this prohibition normally applies after the food is sold and consumed, and its enforcement may be long delayed, for various reasons.

Food and Drug Commissioner Larrick recently said:

> It will take the FDA 25 years to recheck the safety of the colors alone, which are regulated by the FDC Act; and a normal food additive testing may require at least 2 years.

Moreover, in such an enforcement proceeding the Government has the burden of proving that the food is unsafe, whereas this requirement would instead compel the manufacturer of a food to prove in advance that it is safe.

In short, such a food-pretesting requirement would supplement the act's existing pretesting requirements for new drugs, enacted in 1938, and food coal-tar colors, also enacted in 1938, and pesticide chemicals that may contaminate natural food, enacted in 1954.

The Federal Meat Inspection Act of 1906 is also a precedent, because it imposes a similar requirement for meat and meat-food additives; and we may further cite the Federal pretesting legislation for biological drugs—including any virus, serum, toxin, or analogous product—long since enacted, and with which this committee is quite familiar.

We should go on to say that the FDA officially states and documents the preventive need of such a food testing amendment. Commissioner Larrick has recently said:

> We estimate that today there are about 700 substances that people think of as "chemical additives" that go into food. And of that 700, we think about 150 have not been adequately tested.

That the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, known as the Delaney committee, reported this need in 1952—House Resolution 74, 82d Congress, 1st

session; House Report No. 2356, 82d Congress, 2d session—and that further evidence of it will doubtless be adduced at these hearings.

But we add that legitimate food manufacturers, which I represent, now voluntarily recognize that need and cooperate with the FDA in implementing it, as a rule.

For all these reasons my association endorsed the principle of an FDC Act amendment for such a food-testing requirement, at the 1950 hearings before the Delaney committee and again at the 1956 hearings before a subcommittee of this committee. And the record will show, I believe, that this amendment was first publicly suggested in my 1948 address to the division of agricultural and food chemistry of the American Chemical Society in Chicago.

The fundamental importance of this amendment is emphasized by saying that it would mark the most significant advance in our national pure-food law in its entire history. Consequently, the question before this committee is not whether such an amendment ought to be enacted, but rather what its form shall be. That question has been an extended issue between the FDA and the food and chemical industries; and the time has now come for Congress duly and expeditiously to resolve it, in a balanced way that equally protects the consuming public and the legitimate regulated industries.

To do so, and as previously noted, we should first analytically review the responsible administration amendment proposed by H. R. 6747 through a constructive and friendly approach to it, for the purpose of determining whether it is drawn in the right legislative terms and pursuant to the right legislative policy. And in doing so we should give appropriate comparative regard to the industry amendments proposed, legitimately proposed, by H. R. 366 and H. R. 8390, and the parallel bill introduced by Congressman Wolverton, and also to the distinctive amendment proposed by H. R. 8112.

But any discussion of the amendment before us should be introduced by two comments. The first comment is that it will not apply to food coal-tar colors, because they are separately regulated by the FDC Act to the same testing effect; and we suggest its revision to recognize that fact.

The CHAIRMAN. At this point, Mr. Dunn, may I inquire, do any of these bills go that far?

Mr. DUNN. No, sir. Food coal-tar colors are separately regulated by the FDC Act. But we should add that an industry revision of the act's general coal-tar color law is now being developed, whereby it will broadly apply to all color additives from a vegetable, animal, or mineral source, and not to coal-tar colors alone.

The second comment I should make is that this amendment will likewise not apply to meat and meat-food products, as later noted, because they are instead regulated by the Federal Meat Inspection Act to the same testing effect. And we also suggest its revision fully to recognize that fact, which it does not presently do.

You will see, Mr. Chairman, that I am following your request of educationally explaining the whole background of this situation so that the committee will duly understand it, I hope.

Mr. DIES. What you are now suggesting is that this bill should clearly except these other bills?

Mr. DUNN. Exactly.

Mr. DIES. These other laws.

Mr. DUNN. Because——

Mr. DIES. You think the present bill goes far enough in this regard?

Mr. DUNN. Exactly. Because there is no dispute about that point.

Now, the food-testing amendment of H. R. 6747 is appropriately divided into three basic parts: The first part is a proposed definition of the term "chemical additive," for the purposes of this amendment. The second part is a proposed regulation for such an additive. And the third part is a plan for an optional review of that regulation. But this amendment also contains other related provisions, of which three now invite our consideration.

The first provision gives this amendment the following citation name, to wit, "Chemical Additives Amendment of 1957." But that name is inaccurate and misleading. For such amendment is not actually confined to chemical additives in their limited industrial conception, and, instead, it broadly defines the term "chemical additive" to mean any deliberate food additive, as provided.

Hence, the correct name of this amendment is "Food Additives Amendment of 1957," if it is then enacted, as H. R. 366 and H. R. 8112 and H. R. 8390 and the parallel bill by Mr. Wolverton provide; and consequently we suggest its revision accordingly, and to substitute "food additive" for "chemical additive" throughout it.

We presume that the FDA gave this amendment a chemical additive name to emphasize that it mainly applies to such industrial additives, to tie this amendment into the aforesaid House report on chemical additives in foods and cosmetics, and to give it a strong congressional and popular appeal.

But an inaccurate and misleading name for this amendment is not required to secure that appeal for such an amendment. Moreover, a chemical additive name for it may be construed to imply that our manufactured foods are now widely imperiled by injurious chemical additives, which is not so, as the FDA itself will certify.

The fact is that this amendment is basically a preventive one, to make certain that such additives will not be used hereafter, aside from its incidental application to old additives.

The fact is, also, that our people now consume pure and safe foods and enjoy the highest food standards of living, as a rule, subject to any incidental exceptions which the FDC Act was enacted to correct. We should go on to say that a food additive name for this amendment is further better, to distinguish it from a similar cosmetic additive amendment also before Congress.

The second provision, incidental provision, inviting our attention at this time, is that this amendment will take effect on the 180th day after its enactment, subject to 2 exceptions.

The first exception is the sound one, in effect, that industry compliance with this amendment may voluntarily begin after its enactment and before the aforesaid effective date, on a discretionary basis.

The second exception is a very involved one. For it is, in effect, that where a regulated food additive was used immediately before the enactment of this amendment it shall not apply to such preexisting use, until that use has been administratively evaluated thereunder but without opportunity, however, for a review of an adverse evaluation. Or alternatively, and if earlier, until the expiration of either 1 year after the effective date of this amendment or any additional delay administratively granted which may not exceed 2 years after that date.

We suggest that this exception should be fairly revised to eliminate the second "until" clause and to extend the first "until" clause whereby it includes any review period.

The third provision is a sound one copied from the new drug and pesticide chemical laws of the FDC Act. For it authorizes the administrator of this amendment to exempt from it any regulated food additive and any food bearing or containing it, intended solely for investigational use by qualified experts.

Now, as stated, the first basic part of the amendment before us is a proposed definition of the term "food additive"—substituting it for the term "chemical additive"—for the regulatory purposes of this amendment, which governs its product application.

The definition provides, and it is an involved one, that this term means, subject to three exceptions later stated—

> any substance the intended use of which results or may result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended to preserve or alter food or for any other purpose in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any radioactive material intended for any such use or as a source for the irradiation of food), if such substance is not *generally recognized*—

I emphasize the term "generally recognized" because I will later consider them—

> among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use.

Now, the first exception from this definition is a pesticide chemical, because the FDC Act elsewhere similarly regulates it. The second exception is any old food additive administratively sanctioned or approved prior to the enactment of this amendment. That exception would apply to additives sanctioned by food identity standards administratively established under this act, and those administratively approved by informal advisory opinions.

We suggest that this exception be revised to provide for a summary administrative publication of all such exempted food additives before this amendment becomes effective, for industry guidance and public information, and that it be further revised to provide that such prior administrative approval of food additives shall not be subsequently administratively withdrawn without notice and an opportunity for hearing to all interested persons, who are principally our food manufacturers, as H. R. 8112 provides.

The third exception is any old food additive administratively sanctioned or approved prior to the enactment of this amendment, under the Federal Meat Inspection Act. But this exception is an unnecessary and unwarranted one, which therefore should be deleted.

For the FDC Act broadly exempts all meats and meat-food products from its provisions, to the extent that the Federal Meat Inspection Act applies to them; it does apply to their additives, and it is instead administered by the Secretary of Agriculture.

Moreover, this exception is misleading and invites its administrative misuse, because it implies that the proposed amendment of the FDC Act before us can more or less regulate new additives in meats and meat-food products, which is not so, and that is not so because of their above exemption.

Hence such amendment should be still further revised to eliminate its reference to a food additive derived from an animal, in proposed section 409 (c) (3), and to add a provision which squarely provides that this amendment shall not be construed to regulate meats and meat-food products exempted from this act, and regulated by the Secretary of Agriculture instead.

Now, returning to the basic definition of a food additive proposed by the amendment before us, which controls the whole application of the definition, the purpose of such definition is clear. It is to make this testing amendment regulate any substance deliberately added in the manufacture, and so forth, of a food, which does or probably will directly or indirectly become a component of it or otherwise significantly affect any characteristic of it—for example, its appearance, flavor, texture, palatability, nutritional value, or keeping quality—if and to the extent there is any real scientific question about its safe use under the conditions of its intended use.

Hence this amendment would not apply to normally safe food additives of agricultural and farm origin; it would principally apply to food chemical additives in an industrial sense, where they should be scientifically tested for safety, and such additives will be infinite in number and kind in the long view, because they represent the area in which progress will be mainly achieved in the improvement of our food manufacture and products.

But while the purpose of the aforesaid definition of a food additive is clear, it is manifestly drawn in a very complex and obscure form. For this reason, we annex a suggested revision of it, which reorganizes its terms and improves their statement, and we recommend that this committee review the similar definitions proposed by H. R. 366 and H. R. 8390, and the complementary supplemental Wolverton bill in particular.

Moreover, because this definition is drawn in an obscure form, we also suggest that it be revised to provide that the administrator of the FDC Act shall advise interested persons on its product application, upon their request or on his own initiative. This revision, I emphasize, has great practical importance, and it is one that does require justice to the regulated industries, from the standpoint of their honest compliance with this new equipment.

The food-additive definition under review is principally obscure, because of its governing "generally recognized" clause, to which I have previously referred. For that clause literally makes this proposed testing amendment regulate every deliberate food additive, except as provided, which is not generally recognized by qualified scientific experts as safe for use under the conditions of its intended use.

But at best it may be difficult and, in fact, it may be impossible for a regulated additive or food manufacturer always to learn whether a new food additive, for example, is generally recognized by such experts as safe for use under these conditions, especially where they are new; and the definition does not say how general this recognition must be.

The manufacturer may and should practically consult the available scientific literature in point; and he may and should also consult available scientific experts, who are qualified in the circumstances to advise him—which is reasonably enough to accomplish the protective purpose of this amendment.

Hence, we suggest that the committee study the question whether such definition should not be soundly and fairly revised with respect to this generally recognized clause. We have reluctantly omitted that revision from the annexed suggested revision of this definition, because the new drug and pesticide chemical laws of the FDC Act each contain a similar "generally recognized" clause in their analogous definitions. And also because these laws have been practically successful, notwithstanding the obscurity of this clause and because it has been given a reasonable construction of necessity.

But Congress is now originally reviewing the merit of this clause in a new food-additive amendment of this act, and the regulated food-additive and food-manufacturing industries have the right to question its manifest unreasonable obscurity. We should note that the analogous coal-tar color law of this act does not contain such a governing clause.

This proposed definition of a food additive in the administration bill also invites three further important comments. The first comment is that it strictly limits the testing amendment before us to the question whether the additive is safe; and it does not refer to the additive's functional value, which this amendment then unwarrantedly makes a controlling factor, as later explained.

The second comment is that while this definition basically applies to new food additives, whereby it is a pretesting amendment, it also reaches old food additives to the extent their safety has not been scientifically established by prolonged use, whereby it becomes a testing amendment. We suggest that the definition might be appropriately revised to omit the qualifying adjective "prolonged."

For the basic question presented here is whether the safety of a particular food additive has been established by its use, from a scientific viewpoint; and other circumstances of its use may determine that question. For example, where a food additive is used in a scientific institution, such as a hospital, and its safety is there scientifically controlled, the fact of its prolonged use is not material.

We should go on to note that some of my food manufacturers have argued that this amendment should not reach back to old food additives, whose safety was not administratively questioned before its enactment.

But that argument is not sound. For the FDA advises that about 150 food chemical additives are now being used which have not been adequately tested for safety; and experience has demonstrated that a further scientific investigation of such an additive may hereafter establish that it is unsafe, notwithstanding it was previously deemed safe, which was the case with respect to common salt.

The third comment is that this definition of a food additive also reaches a substance directly or indirectly added to a food through its container. The similar amendment of H. R. 8112 further and specially deals with that situation, and we suggest that this committee study its provisions accordingly. They are better and appropriately discussed by the food-container industry.

As likewise previously stated, the second basic part of the amendment before us is a proposed law to regulate a defined food additive, for the protective purpose of such an amendment. This law is contained in numerous and measurably complex provisions, which must be put together.

It is generally modeled on the supplemental pesticide chemical law of the FDC Act, which is notorious for its verbosity, and it is far more technical than the parallel new drug law, which is a broader and more active one in its practical operation.

Hence we suggest that this law be generally revised to a maximum indicated extent for simplicity and clarity, and to correct it as hereinafter and otherwise soundly suggested.

Stripped of its legal phraseology and reduced to its practical essentials, this law may be summarily explained as follows, from the standpoint of its major new additive and working industrial application: such an additive, or a food bearing or containing it, is adulterated and therefore prohibited by the FDC Act, unless—

(1) The additive has been adequately pretested through appropriate scientific procedures to determine whether it is safe for use under the conditions of its intended use;

(2) This pretesting apparently establishes that it is safe for use under such conditions;

(3) The pretesting and specified related data—including that on the additive's functional value—have been fully submitted to the administrator of this act, who as stated is the Secretary of Health, Education, and Welfare, acting through the FDA, which actually administers the act;

(4) He, the administrator, has administratively evaluated said and other pertinent data before him and reached an opinion that the additive is actually safe for use under the intended conditions of its use or other conditions prescribed by him; and

(5) He has issued an order establishing an administrative regulation permitting its use, within a stated time, which is governed by declared safety factors and has a general industry application.

Now, that is the basic law before us, but this law does not, as it should, expressly detail all of these operating elements of it, essentially, which is largely done in the similar amendments proposed by H. R. 366, by Mr. O'Hara, and H. R. 8390, by Mr. Harris, and the similar bill by Mr. Wolverton, and these essential details are mostly left implied, which is not a good state of this law.

Hence, we suggest its correction accordingly. Then this law adds implementing terms. They provide as follows: Such an administrative regulation, which is the control factor, administrative permissive regulation, may be initiated by any interested person, who is principally an interested manufacturer, through a petition to the administrator, which must set forth the proposed regulation and state reasonable grounds to support the petition for it; and such regulation must be published within a certain time.

The administrator may then alternatively issue an order denying this petition, for reasons cited, instead of establishing a regulation in accordance with the petition. Moreover, the administrator may himself initiate a proposed food additive regulation, in his discretion or upon request by an interested person, and it must likewise be published before he issues an order establishing it.

This regulation would be the procedure, that is, the administrator's proposed promulgation would be the procedure by which the administrator would challenge the safety of an old food additive.

We should go on to say that all administrative orders for a food additive, however proposed, whether by the administrator or an interested person, are effective on their publication, unless they are stayed by the review action later described, and that their issuance is uniformly governed by the Administrative Procedure Act.

This proposed law, which we now have before us, invites numerous further constructive comments. The first comment is that it radically differs from the new drug law of the FDC Act, because its administrative regulation has a general industry force; whereas an effective application under the latter law is an individual one.

The second comment is that this law does not accurately define the standards controlling an administrative regulation under it, that it defines no standards for an order denying the petition for a proposed regulation. Hence, we suggest its revision to correct that important situation.

The third comment is that this law does not describe the appropriate scientific procedures to be industrially used under it; and we suggest its revision to provide for the administrative publication of such procedures in an appropriate form, for industry guidance, because there must be these investigatory or scientific procedures to be used both by the FDA and the industry, and they both should be equally informed what they are in order to comply with the law.

The fourth comment is that this law should be revised broadly to provide that all relevant safety factors shall be considered by the administrator in determining whether a food additive is safe under the conditions of its proposed or specified use, where now the bill simply specifies some of them.

The fifth comment is that this law should be revised to make certain that an interested manufacturer need not propose a formal regulation for a new food additive, because such a requirement would be unduly burdensome to smaller manufacturers; and that it should also be revised to eliminate the requirement that a manufacturer's petition for such an additive regulation must be supported by reasonable grounds stated. For such a petition should be an absolute industrial right, and the administrator may deny it for cause.

The sixth comment is that this law should be revised to grant an administrative hearing to a manufacturer proposing a food additive regulation or interested in one proposed by the administrator, upon request, before it becomes effective and pursuant to the Administrative Procedure Act. For such law now provides for this hearing only after the regulation is effective.

The seventh comment is that this law should be revised expressly to provide, as H. R. 8390 does, that the administrator shall hold the pretesting and other data industrially submitted to him in confidence, except where their disclosure is required either to protect the public health or in an enforcement proceeding under the FDC Act.

That provision would supplement the related one now in H. R. 6747, which amends section 301 (j) of this act, to a more limited extent, in order to complete its just protection of the regulated industries in the circumstances thus presented.

We should next go on to mention three more industrial objections to this proposed law. The first objection is made by some food manufacturers to the provision requiring the publication of an industrially

proposed regulation for a new food additive, on the ground that it may reveal a valuable manufacturing secret to competitors. But this objection we deem unsound, aside from a patent answer, for the Administrative Procedure Act requires that publication; and it will be necessarily made in any event, if such regulation is administratively established and because such act likewise requires its publication. That act, the Administrative Procedure Act, likewise requires its obligation of publication.

The second objection is made by more food manufacturers to the provision of this proposed law which empowers the administrator to issue a regulation for a new food additive, which administratively prescribes conditions for its safe use that differ from those industrially proposed. But this objection is also unsound, because that situation is inherent in a law of this sort; unless it is here revised to confine the administrator's safety evaluation of a petitioned additive to the conditions industrially proposed for its use, whereby a manufacturer would then have to propose a new regulation therefor which complies with the administrator's opinion with respect to the safe conditions of its use.

The third objection is a very important one, to which I especially direct the attention of the committee, and it is strongly made by all food manufacturers, legitimate food manufacturers, I represent, as a rule. It is an objection to the provision of this proposed law, which prohibits the administrator from issuing a regulation permitting any food additive that is inherently a poisonous or deleterious substance, which may legitimately be a controversial scientific question, unless the related data before him establishes, which also may legitimately be a controversial scientific question, that such additive has a functional value; notwithstanding—and this is the point—that the administrator finds on the basis of all the related data before him that such additive is actually safe for use under the conditions of its intended or prescribed use.

We maintain that this provision is clearly unwarranted; and we suggest that such law be revised to eliminate it. For, in the first place, and as we have previously seen, the proposed definition of a food additive in this law strictly and exclusively confines it to the question whether such an additive is safe for use under the conditions of its use.

Hence, the amendment before us is solely concerned with the safety, in its basic conception—is solely concerned with the safety of regulated food additives; if they are administratively found safe under the permitted conditions of their use, its law is fully satisfied, and the basic pure-food law of the FDC Act is also fully satisfied, because it is prohibitively concerned here only with the question whether a food is unsafe.

In the second place, this proposed law expressly repeals the act's existing—called the per se—rule of food adulteration, it expressly repeals this rule, which automatically outlaws any deliberate food additive that is inherently a poisonous or deleterious substance—except where its use is required or cannot be avoided, in which event its quantity must be safely limited by an administrative regulation which has not yet been issued with respect to such an additive itself in any instance, and it expressly substitutes the new practical and realistic rule

that such an additive is permitted under this FDC Act, if it is actually safe under the conditions of its use.

For, in illustration, such an additive may be unsafe in a greater quantity, whereas it is safe in a lesser quantity, as in the case of common salt.

This fact is now recognized by the FDC Act through its aforesaid exception, and it is also recognized by this proposed amendment of it, which permits a food additive notwithstanding it is inherently a poisonous or injurious substance and if it is actually safe under the conditions of its use.

In the third place, where a food additive is actually safe under the conditions of its use, the question of its functional value, that is, its industrial functional value, is clearly one for a food manufacturer to decide in his discretionary exercise of the food-manufacturing art; and it is not one for the Government to decide under a pure-food law, directed to assure the safety of food and not its functional use.

Moreover, our great food-manufacturing industry—and we have the finest food-manufacturing industry in the world—has exercised that art to provide our people with the highest food standards of living ever achieved anywhere; and Congress should do nothing to stop that essential progress of our country.

But the FDA will reply that food additives should not be used where they are inherently poisonous or injurious and unless they have a functional value, as a public health policy; and also from the standpoint that their accumulated use may eventually imperil the public health.

This reply, however, will not stand analysis. For the FDC Act amendment before us is, and should be, solely concerned with the safety of a defined food additive, and it insures that safety, and it expressly provides that in determining this question the administrator shall give due regard to the cumulative effect of such additive on public health, in the long view, so that under the bill as it is now drawn and controlled by its safety factors, the cumulative effect of any additive must be considered by the administrator in determining its safety—which is right and enough.

Now, the third and final basic part of the amendment before us is a plan to review the regulation of a defined food additive, to prevent any arbitrary and capricious and unreasonable administration of this amendment.

Hence, such plan has great industrial importance. And it is one for an optional respective scientific and administrative and court review requested by an interested person, in that order.

We suggest that this amendment be revised to make the optional character of such review clear beyond question. For section 409 (f) proposed by this amendment, as it is now drawn, casts some doubt on that question.

The scientific review is copied from the pesticide chemical law of of the FDC Act; and it should be expressly made subject to all the safeguards of the Administrative Procedure Act, which is now not done.

Hence, we suggest a revision of such amendment accordingly. This review applies within prescribed time limits to an industrially or administratively proposed regulation; and to an order administratively

establishing a regulation or denying it. Thus, it has a broad application.

In doing so, this review reaches any or all of the scientific facts thus presented, in each instance. It is a review independently made by an ad hoc scientific advisory committee of "competent experts," in each instance, qualified to deal with the scientific facts before it, which is selected by the National Academy of Sciences and appointed by the administrator of this act; and either the person who requested such review or the administrator may consult with the committee on the facts referred to it, which is manifestly a fair provision.

The committee must report to the administrator within a prescribed time; and the report must state the reasons for its recommendations.

On receiving this report, the administrator must confirm or modify his related order, or otherwise he must establish or refuse to establish a related regulation. The person requesting the review must pay its cost.

The administrative review, which is the next step in the review plan, is substantially that elsewhere authorized by the FDC Act; and it is governed by the Administrative Procedure Act.

This review is initiated by any person adversely affected by and objecting to an administrative order under the amendment before us. It is made by a public hearing to receive evidence pertaining to the issues, which is operationally conducted by the administrator of this act through a hearing examiner.

He must place in the record any related report by a scientific advisory committee; and a representative of it must then submit to any desired cross-examination.

After the hearing is completed the administrator must publish a final order in point, which must be based on substantial evidence of record, and state the findings of fact on which it is based. We suggest that this administrative review plan be revised expressly to provide, which it does not now provide, that the hearing examiner shall be appointed in each instance as provided by the Administrative Procedure Act, and shall have the functions prescribed by that act, in order that the hearing may be a truly fair and impartial one, as is done under the Federal Trade Commission Act, for example.

This revision has great industrial importance. For the foregoing situation does not obtain where the hearing examiner is an attorney of the FDA, which has previously decided the issues against the person initiating the hearing.

In this connection we note that a bill is before Congress, S. 932, which creates an Office of Federal Administrative Practice to provide for a due appointment of impartial hearing commissioners in order to correct the problem, solve the problem, of having an impartial hearing examiner in every instance.

The judicial review, which is the final review provided by this amendment, is likewise that elsewhere authorized by the FDC Act, as a rule; and it is also governed by the Administrative Procedure Act.

This review is initiated by any person adversely affected by the final administrative order aforesaid, and it is made by the United States court of appeals; whereas that under the new drug law of this act is, instead, made by the United States district court.

Such review by the former court, that is, the United States court of appeals, is dominated by a provision in the amendment before us

that the foregoing administrative findings of fact, on which the order is based, must be judicially sustained if they are supported by substantial evidence when considered on the record as a whole.

We deem that provision to be an inherently unfair one, because the administrator of this act can ordinarily use it to secure an affirmation of his final order, regardless of any evidence to the contrary; and, therefore, the judicial review is ordinarily fruitless and useless.

This basic fact is recognized by the American Bar Association, which drafted and sponsored the Administrative Procedure Act, because it is now developing a revision of this act which, instead, directs that the court shall not accept the administrative findings of fact in a situation like the one before us, where they are clearly erroneous on the record as a whole, which would be a more liberal rule of evidence.

But unfortunately that revision of such act has not yet been enacted, and its aforesaid challenged provision now controls a judicial review of a final administrative order under this amendment; and it may be strongly argued, as the FDA does argue, that Congress should not use the particular FDC Act to revise the general Administrative Procedure Act.

Nevertheless, we maintain that the sound and just rule of evidence in the judicial review under consideration is that the administrative findings of fact must be sustained only where they are supported by the weight of the evidence in the record as a whole, which is precisely what the Federal Commodity Exchange Act now provides.

In view of its precedent and in the interest of procedural justice, we suggest that this committee study the substitution of that rule in the amendment before us, which it has the right legislatively to recommend.

In conclusion, we have now reached the point where we now have before us the provisions of H. R. 6747 for an administration food-additive amendment of the FDC Act, in their practical conception; and this explanatory analysis of it, which I hope is an educational one, Mr. Chairman, reveals two ultimate facts:

The first fact is that this bill should be comprehensively revised to give it a right legislative form. And if the committee can await my return from Europe in September and it desires this, I will then undertake to submit a revision of the bill in that form for its consideration.

The second fact is that the legislative policy expressed by this bill is an administrative procedure one in accord with the Administrative Procedure Act, which places defined food additives under a permissive regulation control by the FDA, in effect, subject to the optional review described. And that was the controversy between the FDA and the industries here before.

My association previously opposed the policy of this permissive regulation control, because it amounts to a Government license of the food-manufacturing industry in a vital area of its future progress; and unnecessarily so, we then believed.

But we are now disposed to approve the policy of this control if it is expressed in a right legislative form, for several convincing reasons, and subject to an important qualifying comment that I will add: The first reason is that the FDA uncompromisingly insists on such a permissive regulation control, on the ground that it will more effectively protect the public health; and we, as an industry, desire to cooperate constructively with it, in every available way.

In addition, the FDA firmly believes that scientific questions under the FDC Act, and under this amendment in particular, are better determined administratively. We respect the FDA, and we recognize its fundamental responsibility to protect the public health, through the FDC Act, which it is duty bound to administer appropriately.

The second reason is that the policy of this control is now firmly imbedded in the new drug, pesticide chemical, food standard, food coal-tar color, and general regulation laws of the FDC Act.

Moreover, the Federal Meat Inspection Act may also be cited as a precedent, together with the Federal biologic drug legislation previously noted; and the Federal Trade Commission Act is also an administrative procedure one.

The third reason is that the amendment proposed by H. R. 6747 contains a provision for an expert and impartial scientific review, which is a new provision in an amendment of this sort, of its permissive regulation control, which would measurably check serious abuse of it.

The fourth reason is that the Judicial Conference of the United States supports the policy of such control, as Judge Biggs testified at the 1956 hearings before a subcommittee of this committee. He did so also on the ground that scientific questions under the FDC Act are best administratively decided, as a rule, subject to a review consistent with the Administrative Procedure Act.

Then there is another reason, Mr. Chairman, which I omitted from my written statement, that should be cited here, why my association has decided to support this control, subject to the qualifying comment which I will now make, and that is this: The late and revered Chairman Priest, of this committee, discussed this amendment at great length with me after the hearings last year, and after he had heard all of the testimony pro and con, and he advised me very earnestly that our great food industry should support the FDA in this situation, provided that the amendment is drawn in a proper form.

Now my qualifying comment is this, and this is a rather important consideration, Mr. Chairman, and I hope that all members of the committee will carefully consider what I now say:

This is my qualifying comment, the qualifying comment of the principal, National Association of Food Manufacturers, that I represent: While the above reasons for the permissive regulation control of food additives have the complete force of their statement, this significant fact remains, and it is an extremely important one from an industrial standpoint.

Many, perhaps most—and I have tried to talk with all of the leading food manufacturers of this country in our organization—many, perhaps most, legitimate food manufacturers remain very uneasy, indeed, over the policy of this permissive regulation control of food additives, because it does involve a drastic Government license of their industry to which they are instinctively and philosophically opposed, and they have always opposed, as this committee knows, in the record of enactment of pure-food legislation down the many years and when I have testified before it; and our industry has always preferred a food law which is drawn in the traditional form of making the necessary protective requirements on an objective basis for their due Government enforcement, which is the state of the present food law of the FDC Act.

Now, these manufacturers, these fine legitimate manufacturers, have no objection whatever to the FDC Act requiring a pretesting of potentially dangerous additives and a submittal of the pretesting and other related data to the FDA for its evaluation in enforcing this act.

What they do not like, instinctively, is that further step made by the amendment before us, which places their necessary food additives under a permissive Government control.

Moreover, while these manufacturers trust, fully trust, the present FDA officials and deem them able and fair and dedicated to the public welfare, they must consider from a long-range standpoint whether other and different officials will hereafter replace them and may misuse such control to injuriously suppress essential progress by their industry in this basic food-additive area.

In view of that situation, I have given very careful consideration, Mr. Chairman, and I telephoned to Chairman Harris about it, to the question whether H. R. 6747 before us could be further revised, after it has been fully revised as it should be revised in its own self, whether it should be further revised on a compromise basis whereby the administrative structure of its amendment is maintained as now, but a provision is added to satisfy this strong feeling of legitimate food manufacturers.

I believe that such a provision is available. It is one that would authorize a manufacturer, for example, adversely affected by an administrative order under the amendment before us, to petition the appropriate United States district court to enjoin that order for cause shown, after due pro and con argument, pending a trial, a de novo trial, on its merits.

This provision would grant such court the discretion to reject that petition for cause shown, so that it would not be mandatory power, and that situation should protect the Government in the circumstances.

But it would have the value of giving the manufacturer this alternative appeal remedy, where it appears needed or advisable in the circumstances, and he feels that he should have the merits of his food chemical additive, his new food chemical additive—which may be immensely important to him, and the production of which may have cost him millions of dollars—decided in this way. A remedy which would be used only occasionally, at most; and certainly it would not be used in a case where a scientific advisory committee has sustained the FDA order in question.

But where it is industrially needed or advisable in the circumstances, this remedy would have a great and just procedural value, for the reasons I have stated.

Then I should add that if the court denies such a petition for an injunction, the standard appeal provisions of the amendment before us would operate; whereas if it grants this petition, the foregoing added provision that we have in mind would stipulate expressly that the relevant pretesting data submitted by the petitioner to the FDA shall be taken as admissions by him, for the purpose of this proceeding.

In short, this compromise provision would operate to meld the proposed administration amendment of H. R. 6747 and the proposed food-industry amendment of H. R. 8390 and the other bills suggested, introduced by Mr. O'Hara and Mr. Wolverton, in particular, on a compromise basis.

Hence, I suggest that the committee duly study the question of such an added provision.

But then I conclude by saying that if the committee rejects this compromise provision, then my National Association of Food Manufacturers approves the administrative amendment proposed by H. R. 6747, provided it is revised in a due legislative form.

ANNEX

We suggest that the definition of a food additive, proposed by the amendment before us, be revised to read as follows, and the significant revision is printed in italic:

(1) The term "chemical additive" means, except as herein otherwise provided, any substance used or intended to be used for any purpose in the manufacture, processing, preparation, packing, or other fabrication of any food, or in the treating, packaging, transporting, or holding of any food—

(*a*) which thus becomes *or could reasonably be expected to become* a component of such food, either directly or indirectly; or

(*b*) which thus otherwise affects *or could reasonably be expected to affect* any characteristic of such food, either directly or indirectly, including any substance intended to preserve or alter such food and any radioactive material intended for use in such food or as a source for its irradiation,

if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate the toxicity of such substance or its other potentiality for *injury to health*, as having been adequately shown through *appropriate* scientific procedures or through (*prolonged*) use in *or on* food to be safe for use under the conditions of its intended use.

(2) *The term "safe for use," with reference to a chemical additive used in or on a food, means it is reasonably probable that such additive can be thus used under the conditions of its intended use without rendering the food injurious to health.*

(3) The term "chemical additive," as used herein, does not include (A) a pesticide chemical in or on a raw agricultural commodity, or a pesticide chemical when intended solely for use in the production, storage, or transportation of any raw agricultural commodity; or (B) any substance used in accordance with a sanction or approval granted pursuant to this act, prior to the enactment of this paragraph.

(The additional similar exception with respect to the Federal Meat Inspection Act has been eliminated, for the reasons previously stated.)

Thank you very much.

Mr. WILLIAMS. Mr. Dunn, I think anyone who has heard your statement will agree with me you are thoroughly acquainted with the subject you have talked about this morning. Certainly your statement points up the complexity of the problem that is before this committee. We appreciate very much your having prepared such a comprehensive analysis of the various aspects of this problem.

There may be questions by members of the subcommittee and ex officio members of the subcommittee, which you might be able to answer, and I would like to ask Mr. Harris if he has any questions, first.

The CHAIRMAN. I believe not, Mr. Chairman, except to say that I am very glad to have had the privilege of hearing Mr. Dunn in his presentation this morning on this very important and highly technical subject.

I recall a previous occasion on which Mr. Dunn last appeared before this committee, and he has always been very helpful. We are glad to welcome you back again.

The presentation you have made does point up the importance of the subject to which this committee must give a great deal of attention and careful consideration.

I have just this one question, and that is, I understood you to say in your statement that legislation in this field is absolutely necessary.

Mr. DUNN. Yes, sir.

The CHAIRMAN. Is that true?

Mr. DUNN. Yes, sir.

The CHAIRMAN. Is that recognized by everyone so far as you know?

Mr. DUNN. There is no dispute on that question in the food-manufacturing industry that I know of.

The CHAIRMAN. In other words, all sides, so far as you know, recognize the fact that legislation is necessary?

Mr. DUNN. Exactly. And we take the further position, Mr. Harris, that the responsible Administration bill should be used as the basis for enacting and developing this legislation, revising it as the circumstances require, and the committee believes, in a balanced form to equally protect the consuming public and the legitimate regulated industries.

These other bills which have been introduced are very valuable, indeed, from the standpoint of comparison, and taking out from them the good features that they have, which should be added to an amendment of this sort.

I participated in the development of the food-industry bills which Mr. O'Hara introduced and which you, Mr. Harris, subsequently introduced, with Mr. Wolverton, in their original conception. And at that time we had no FDA or Administration bill before the committee, so that we were plowing an original legislative path through these food-industry bills.

But now that the FDA—which, after all, administers our great and essential national pure-food law, and is very competent to do so—has now proposed an amendment drawn from the standpoint of its point of view, our position is, that from a responsible standpoint the food industry and I believe also this committee should use that bill as the basis for its development of this amendment, modified as it should be modified from every standpoint.

The CHAIRMAN. Thank you very much.

Mr. WILLIAMS. In that respect, Mr. Dunn, which one of these bills more closely conforms to the views of your organization?

Mr. DUNN. Well, I cannot answer that question "yes" or "no."

I would say this: That H. R. 8390, by Mr. Harris, and the companion bill by Mr. Wolverton, was the bill that the responsible food and chemical manufacturing industries originally developed, with some modifications.

But, a great deal of water, Mr. Chairman, has gone over the dam since we developed those bills, and the principal consideration facing you and facing us at this time is the fact that the Administration itself has now proposed its own bill, and therefore we believe that the food-industry bills, if I may call them such, should be now used for the purposes of reforming the Administration bill, so that we will come out with a bill which melds all points of view in an appropriate way.

The CHAIRMAN. Of course, that will be developed during the course of the hearings. The committee can make the determination later on.

Mr. WILLIAMS. I note that H. R. 8390, which you say is the industry bill, was introduced on June 26, 1957, which is some just 2 or 3 weeks

ago, I believe. H. R. 6747 was introduced in April, which was 2 months prior to the date that the industry bill was introduced, and you mentioned that a lot of water had gone over the dam since the industry bill was introduced, which made you feel that the Administration bill should be used as a basis for consideration by this committee.

Mr. DUNN. Yes, sir. Now, the explanation of that is this: a counterpart of the second Harris and Wolverton bill was introduced last year, and Mr. O'Hara introduced at that time, also, a bill developed by the food and chemical industries, so that there is nothing new about these bills at all, these industry bills. They were before Congress last year. And what is new is the Administration bill.

Mr. WILLIAMS. Yes, sir.

Mr. DUNN. We did not know anything about that at all, until it was introduced.

Mr. WILLIAMS. Mr. Schenck?

Mr. SCHENCK. I have no questions.

Mr. WILLIAMS. Mr. Rhodes?

Mr. RHODES. I have no questions.

Mr. WILLIAMS. Mr. Bush?

Mr. BUSH. No questions except to say that the statement made by you, Mr. Dunn, is certainly very revealing and very factual as to the position of the industry which you represent.

Mr. DUNN. I hope fairly so, sir.

Mr. BUSH. That is all I have, Mr. Chairman.

Mr. WILLIAMS. Mr. Dingell?

Mr. DINGELL. No questions.

Mr. WILLIAMS. Dr. Neal?

Mr. NEAL. I have no questions.

Mr. WILLIAMS. Mr. Loser?

Mr. LOSER. Nothing at all, sir.

Mr. DUNN. I wonder if Mr. O'Hara has any questions? He has been so interested.

Mr. WILLIAMS. I am just getting around to recognizing Mr. O'Hara.

Mr. O'HARA. Thank you, Mr. Chairman.

Mr. Dunn, I note that, as a member of the American Bar Association, you are going over to London, and there you will have a joint conference, I assume with the British bar and perhaps other international lawyers in this field.

Do you know of any legislation that they have which would be helpful to this committee which might induce the subcommittee to await your return?

Mr. DUNN. No.

Mr. O'HARA. I say do you know whether they have any forward-looking food and drug additive laws which are good for us to know about?

Mr. DUNN. This conference, Mr. O'Hara, is a rather historic one, because we have never had one of this sort before, and it will be largely a scientific conference in which the food commissioners of the United States, Canada, and Great Britain will discuss the various scientific aspects of such legislation.

The general conclusion that runs through all of these papers is that there must be legislation to control food additives, and that the administrative authorities should be given the necessary powers to administer such legislation.

Mr. O'HARA. Well, as a member of the American Bar Association for many years, I got their program, and I noticed they were going to dedicate a monument at Runnymede to the Magna Carta.

I thought that would be of interest to some of the members of the committee, because the Magna Carta guaranteed a jury trial, as I recall it. [Laughter.]

Mr. DUNN. Well, that comment is interesting because it fits in with the compromise suggestion which I offered, and which I think must appeal to you. You have got a very mixed situation here, Mr. O'Hara. You have to balance off many different pros and cons and try to reach a just and sound conclusion from the standpoint of all concerned.

We in the food industry feel that we should not be arguing about this bill from the standpoint of the food industry above. We simply serve the American people in providing them with wholesome and pure foods and, therefore, we have a very great responsibility to promote legislation which is necessary to secure the safety of our foods.

We have supported such legislation, as Mr. Harris knows, from its very inception. I cooperated with Senator Copeland in the development of the Federal Food, Drug and Cosmetic Act, and had a very considerable part in the writing of that act. And that was a contribution by the food industry.

Now we are trying to make a contribution in the solving of this complex food additive amendment before you, and our position boils right down to this, Mr. Chairman, that we are in favor of the Administration bill, provided it is duly revised as we have suggested. We suggest that this compromise provision should be added, which will satisfy the objection to the Government license provisions in it, on an equitable basis, but that decision is left with the committee to make.

The CHAIRMAN. Mr. Chairman, will the gentleman yield?

Mr. O'HARA. Yes; I will yield for a question.

The CHAIRMAN. Just a very brief statement to reassure the gentleman from Minnesota, from the questions raised this morning by Mr. Dunn, and those which I can see are going to be raised, I think he can be reassured that Mr. Dunn will have plenty of time to return from Europe before any resolution is reached on this subject.

Mr. O'HARA. Of course, Mr. Dunn, it is true that, under the present Food and Drug Act, the Food and Drug Administration has three remedies if food is being sold to the public which is injurious or deleterious to health: They can go into the district court and obtain an injunction, for one remedy. They can prosecute criminally. Or they can go in and seize the food.

Now, they have that under present law, is that not true, Mr. Dunn?

Mr. DUNN. That is true, Mr. O'Hara, but the point is that the law now applies to a food after it is sold and consumed; whereas the purpose of this amendment is to assure the safety of a food before it is sold and consumed.

Mr. O'HARA. I was the author of a bill during the last session of Congress which provided the same——

Mr. DUNN. What was that?

Mr. O'HARA. I say I was the author of a bill, along with Mr. Priest, which did just that, recognized that principle.

Mr. DUNN. Exactly. It has been your philosophy and it has been our philosophy.

Mr. O'HARA. I got that philosophy from working for a number of years with the food-industry organizations which I think are quite largely responsible, namely, the American Bakers Association, the American Institute of Baking, the American Meat Institute, the Dairy Industry Committee, and the Millers National Federation, who are all quite responsible dealers in foods in this country; are they not, Mr. Dunn?

Mr. DUNN. Very much so. They are fine organizations.

Mr. O'HARA. And I think you will find my bill, H. R. 366, which I introduced at the start of this session of Congress, with one amendment, is similar to the bill that you strongly supported in testimony in 1956 before this committee.

Mr. DUNN. Not only that; I had a very large part in drafting it originally.

Mr. O'HARA. I didn't remember that, but I am happy to have you tell me that. [Laughter.]

Anyway, it does indicate the desire of the food industry for safe, sound, sensible legislation; does it not?

Mr. DUNN. Exactly.

Mr. O'HARA. And would you say that H. R. 366, before the committee, is pretty good legislation still, Mr. Dunn?

Mr. DUNN. It is a good bill, except that it raises the controversial issue which is the heart of this whole legislative problem: Whether an adverse administrative opinion against the safety of a food additive should be reviewed, in effect, by a de novo trial through the district court, which is the heart of your bill, or——

Mr. O'HARA. But you rather substantially support that in your various statements of objections to the Administration bill; do you not?

Mr. DUNN. Well——

Mr. O'HARA. I mean, you go in by injunctive relief, but there would be a trial; would there not?

Mr. DUNN. What I say is this: Your bill makes it mandatory for the district court to determine, by a declaratory judgment proceeding, whether an additive is safe or not, before the Administration has condemned it.

Now, my position is quite different at this time. I am trying to say that, first, the Administration bill should be revised to reduce it to the right legislative form, and it needs a very thorough revision in that respect.

And that, secondly, to meet the objection of the legitimate food-manufacturing industry, which is so widespread, there ought to be some way in this bill to provide for a de novo court review of the issue where the Administration has adversely condemned a food additive; that a compromise provision might well be to vest a discretionary power, not a mandatory power, in the United States district court to undertake that de novo rule for cause shown, so that when the petition for review is presented to the district court, the Government would state any reasons why that procedure is not a good one.

For example, it may state, as Commissoner Larrick has often said, that the scientific determination of the safety of the additive in question may take at least 2 years, which is the normal period for determining the safety of an additive by a scientific process; and that, therefore, it would not be feasible, the Government would not be in posi-

tion at the time of the proposed court proceeding to present its testimony.

Now, if the court was persuaded that it would be against the public interest for that or any other reason, then the petition for an injunction proceeding would be denied.

But if, on the other hand, the court was persuaded by the argument of the manufacturer, a legitimate manufacturer, that there should be this de novo inspection trial instead of the appeal procedures as provided by this act, then there would be an opportunity to have it.

Mr. O'HARA. My position is always it should be a matter of right, not whether the judge wanted to work on the case, and I still think that is a sound approach to as important a problem as this might be, Mr. Dunn, and I hope after you visit the dedication of the Magna Carta that you will agree with me.

Mr. DUNN. I respect that position, Mr. O'Hara, and I expect to attend that dedication ceremony, and I know I will be very much inspired by it.

But we still feel the United States district court ought to be given the discretion, representing the people of this country, in balancing the public interest, to reach the decision whether that review ought to be made, or whether the Administration review procedures should be followed.

Mr. O'HARA. Mr. Chairman, I thank you very much.

Mr. WILLIAMS. Mr. Dunn, along those lines, in writing any legislation that comes from this subcommittee, I want to be perfectly sure and satisfied that we do not deny any existing civil rights of any of our people. I want to be sure that you have the same thing in mind.

Do you have any question in mind, Mr. Heselton?

Mr. HESELTON. No.

Mr. DUNN. Mr. Chairman, may I ask a final question of you? Do you want us to submit a revision of this bill in September, or do you not want us to?

Mr. WILLIAMS. Mr. Dunn, that is a question I do not think anyone can answer at the moment. If we have not completed work, I am quite sure we would welcome any suggestions which you or any other interested parties might have with respect to revision.

As the chairman of the full committee stated a moment ago, it is highly doubtful whether we will be able to finish consideration of this bill by September.

I do have 1 or 2 questions with regard to your testimony and along the lines you has just mentioned.

I note that you made numerous suggestions for modifying and revising this legislation, one in particular with respect to the definition of the term "food additive" or "chemical additive."

However, and I believe you refer to it in the annex of your statement, you submitted suggested language for only one of these amendments, and that is with respect to the definition of the term.

I am wondering if you plan to submit suggested amendments along the lines of the other amendments or modifications suggested in your testimony?

Mr. DUNN. Well, the amendment in the annex to my statement, Mr. Chairman, contains one revision we suggest, subject only to the question whether the "generally recognized" clause should be modified.

And on that point I am quite firm in my own belief that it should be reasonably modified; and other revisions will be submitted.

You can see, as a layman, I think we can all see, that you should not practically require a manufacturer to do any more than this, from the standpoint of an appropriate scientific investigation by experts: First, to consult the available scientific literature on the point. This is what they do, anyhow.

Secondly, to consult available scientific experts who are competent to advise on the question.

Now, if you have a clearance from both of these sources, you should be in a position to go ahead, whereas the amendment as it is now drawn says, in effect, that you cannot use an additive unless it is generally recognized by all scientific experts, who are qualified on this subject, as safe for use under the conditions of its intended use. Does it mean scientists in Europe, for example?

I am counsel individually for many food manufacturers. We cannot go all over the United States picking out every single scientist that there is who might have some knowledge of this subject, and then reach a conclusion that, on the basis of their advice, it is safe for use.

And we certainly cannot consult the scientists in Europe who are qualified, equally qualified.

It is just commonsense that this formula in the definition of "food additives" should be limited to the point that the manufacturer should only be required, first, to consult the available scientific literature in point, which is in every good scientific library; and, secondly, that he should consult competent scientific experts on this question.

But when you tell him he must consult everybody, why, it is impossible. And that is literally what this definition says. It has been in the law all these years, I realize that.

I am counsel for the pharmaceutical industry as well, and when it was added to the new drug law in 1938 we did not object to it because that new drug law went through so fast, because of the tragic accidents with some elixir out in Tennessee was pressing Congress to enact a new drug law at once, and there was practically no consideration by the Congress.

Mr. HESELTON. Mr. Chairman, one question.

I notice on page 17 the word "prolonged" in parentheses as a suggested amendment. Do you intend to include that in the suggested amendment?

Mr. DUNN. No, sir. I suggest that it be excluded, simply because the generic question here, the basic question, is whether any use has——

Mr. HESELTON. You would leave it "through use in or on food"?

Mr. DUNN. That is right.

Mr. HESELTON. Yes.

Mr. DUNN. That is enough, because there are considerations other than time which enter into this question.

Mr. WILLIAMS. Are there any further questions of Mr. Dunn?

Mr. Dunn, the House is in session, and it is going to be necessary for the committee to adjourn.

We would like to thank you very much for your comprehensive and clear testimony which was given to us this morning. I think a lot of us, myself included, have a new appreciation of the problem we are confronted with in this additive field.

There are any number of questions that all of us, I am sure, would like to ask you, which we will have to defer for later witnesses. And I am reasonably certain that before we take final action on this legislation we will have time to consult with you again, following your return from Europe.

Mr. DUNN. Mr. Chairman, may I suggest this: In September, after you have completed these hearings, if you want any answers to specific questions from our standpoint, or if you want us to submit a revision of this Administration bill, we will be glad to do it, because we want to cooperate in every way to expedite the enactment of this amendment. We are sorry it will not be enacted at the present session of Congress.

Mr. WILLIAMS. Thank you very much, Mr. Dunn, and the committee hopes you have a very pleasant trip to Europe.

The committee will stand in adjournment until 10 o'clock.

(Whereupon, at 12: 05 p. m., the subcommittee adjourned, to reconvene at 10 a. m., Tuesday, July 16, 1957.)

FOOD ADDITIVES

TUESDAY, JULY 16, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334, New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. The committee will be in order.

This morning it is our pleasure to have with us Dr. R. Blackwell Smith, president, Medical College of Virginia, Richmond, Va.

Dr. Smith is testifying at the invitation of the subcommittee in order to present to the subcommittee some technical background information for chemical additive legislation. Speaking for myself, I feel greatly in need of being educated as to just what scientists are doing when they undertake to test the safety of chemicals whose addition to some food is contemplated by some food manufacturers or processors.

I would like to know something about the scientific disciplines which are involved in such tests; what kind of tests are made; what the considerations are which are involved in the evaluation of these tests; whether the measurements used in these tests are exact or whether educated guesses are involved on which scientists may differ.

I believe that probably most of the other members of the subcommittee are in the same position in which I find myself. I feel that we cannot pass any intelligent judgment on the bills before us unless we have at least a minimum of an understanding of the scientfic problems involved.

Therefore, we are very happy that Dr. Smith has kindly consented to undertake the difficult task of trying to give this committee some background information in the field of chemical additives.

I understand that Dr. Smith is a member of the Food Protection Committee of the National Academy of Sciences, and I would like for him to explain for the record in a few words the history and purposes of that Committee, and what it has done so far in this field.

In this connection, I would like to take a moment to refer briefly to the announcement which I made previously that a panel of scientists would testify before this subcommittee on the scientific aspects of chemical additives.

On June 26, 1957, I addressed a letter to the National Academy of Sciences requesting the selection of such a panel and the designation of an impartial chairman to lead such a panel discussion.

At this point in the record, I am including a copy of my letter to Dr. Detlev W. Bronk, President of the National Academy of Sciences.

(The letter referred to is as follows:)

Dr. DETLEV W. BRONK,
President, National Academy of Sciences,
Washington, D. C.

DEAR DR. BRONK: The Subcommittee on Health and Science has pending before it a number of bills dealing with food additives. Hearings on these bills are contemplated for the second half of July.

As you know, food additives have been the subject of extensive hearings in previous Congresses but so far no legislation has resulted because of continuing disagreement with respect to legal and governmental problems involved in this legislation.

It is my intention, in the hearings before the subcommittee, to have the scientific problems underlying this legislation discussed separate and apart from the governmental and legal aspects.

I recall that during the 84th Congress, when controversial scientific questions arose with regard to the safety and efficacy of the Salk vaccine, you assisted the committee in selecting a representative panel of experts qualified to discuss the scientific problems involved and in suggesting an impartial chairman who presided over the panel discussion.

The Salk vaccine presentation panel was outstanding in every respect. A similar discussion of the complex scientific problems involved in the case of food additives appears to be an excellent method of presenting to the members of the subcommittee, the Congress, and the general public, the scientific background of the pending bills.

I would therefore like to request your assistance in selecting a panel of experts and suggesting an impartial chairman for the purpose of discussing before the subcommittee the scientific problems involved in testing and evaluating the safety of food additives.

It would seem to be that the procedure to be followed by the panel might be modeled after the procedure followed in the case of the Salk vaccine panel. Each panel member would be given an opportunity to make a brief statement, to be followed, under the guidance of the impartial chairman, by questions from other panel members and members of the subcommittee.

I have requested Mr. Kurt Borchardt of the committee staff to assist you and the panel in any possible way in preparing for these hearings, and I would like to suggest that you feel free to call upon him to arrange for all necessary details.

Other pressing committee business unfortunately prevents me at this time from setting a definite date for the panel discussion. As I have indicated earlier, I anticipate that the hearings will take place during the latter part of July. As soon as I am in a position to do so I shall communicate with you further with regard to a definite date for the panel discussion, and I hope that in the meantime you will be able to make at least a tentative selection of the panel members and the panel chairman.

With kindest regards, I am,

Sincerely yours,

JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science.

Mr. WILLIAMS. On July 2, 1957, Dr. Cornell replied to my letter of June 26, and I was glad to learn that the Academy was willing to undertake the task of suggesting such a panel and selecting an impartial chairman.

Unfortunately, the several scientists suggested by the Academy to serve as impartial chairman or alternates were unavailable on the dates for which the panel discussion was originally scheduled, namely, July 15 and 16.

In view of the fact that the session of the Congress is drawing to a close, the subcommittee did not want to postpone these hearings, although the subcommittee would have preferred to open these hearings with the panel discussion as originally scheduled.

As things now stand, we are planning to hold the panel discussion at a later date, and we are trying to get in touch with the scientist

who was suggested by the National Academy of Sciences to serve as impartial chairman.

Since he happens to be on the other side of the world, communications are difficult and time-consuming, but every effort will be made to arrange for a date in the near future to get the panel together.

I wanted to make this explanation in order to make clear that there is no mystery about the panel discussion and that the subcommitee would like to have such a discussion because it firmly believes that it will contribute greatly to an understanding of the problems involved in this legislation.

However, the short time that was available for planning these hearings and the fact that July and August are good months to take vacations—except for Members of Congress—have made it impossible to go through with our original plans.

I would like to apologize to Dr. Smith for taking so much time in this introduction, but I thought I had better put all the cards on the table with regard to the scientific panel discussion.

We are grateful to Dr. Smith for volunteering his services at this point in the hearings, but I wanted it understood that we are still planning to schedule the panel discussion for a later date.

I understand that Dr. Smith does not have a prepared statement. But, Dr. Smith, we would like for you to appear before the committee as if we were your students. Just consider the committee members, the witnesses and the audience as your class this morning, and proceed in your own way to explain the problems involved.

For the record, however, Dr. Smith, will you please give in a few words, in the beginning, your educational background, and the positions you held prior to becoming president of the Medical College of Virginia?

The committee will be very happy to heard from Dr. Smith at this time.

Mr. HARRIS. Mr. Chairman, with the indulgence of Dr. Smith and the Chair, at this moment I would like to say just a word about this panel discussion you mentioned.

I knew, of course, of the efforts to bring about the discussion prior to the hearings. I was somewhat impressed with the idea, and still am.

I would like to suggest, Mr. Chairman, that when you determine the date of the panel discussion, you try to work it out a few days in advance, and then give every member of the full committee notice of it and invite them to attend the subcommittee session at that time for the purpose of listening to the discussion.

I think it is a very important discussion, and I believe all the 33 members of the full committee should avail themselves of the opportunity to join you and to become educated on the scientific aspects of this legislation.

We need to learn a lot about it, and I think such procedure would be highly desirable, and I would like to suggest that you do that, if it meets with the committee's own schedule.

Mr. WILLIAMS. I am sure that would meet with the approval of the subcommittee, and as soon as we can get this panel set up, we would be delighted to have the full committee meet with us. We will follow your suggestion.

I am pleased to recognize Dr. Smith.

STATEMENT OF ROBERT BLACKWELL SMITH, JR., PRESIDENT, MEDICAL COLLEGE OF VIRGINIA, RICHMOND, VA.

Dr. SMITH. Mr. Chairman and gentlemen of the committee, thank you very much for your willingness to listen.

I should like to state for the record, I appear at Mr. Borchardt's invitation and not strictly as a volunteer. I was glad to come.

I should like to emphasize at the outset that I appear as a private person, and not as a representative of the food protection committee of the National Research Council or of any other group.

As Mr. Williams has pointed out, I have no prepared statement, and when Mr. Borchardt called me on Friday and I told him I would be unable to prepare a statement, he said, "Good. It would spoil the whole thing if you had one."

For the record, I should like to mention a small publication called Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Foods, printed by the National Research Council first in 1954, and reprinted in 1957, in which the general problems with which this committee is now concerned are discussed rather briefly, but without omitting, I think, any important considerations.

Mr. WILLIAMS. Doctor, before you get into your testimony, would you, for the sake of the record, give us a brief history of your personal background, your qualifications to speak to this subject?

Dr. SMITH. Excuse me, sir.

Mr. WILLIAMS. Also, I think it would be well to inform the committee as to just what the food protection committee is, its functions, and how it was set up, a little bit about the history of that.

Dr. SMITH. My name is Robert Blackwell Smith, Jr., and I was born in Petersburg, Va., in 1915.

I attended college first at the Medical College of Virginia, where I received the degree of bachelor of science, with a major in pharmacy, in 1937.

In 1938, I received the degree of master of science from the University of Florida, having done major work in pharmacology and minor work in bacteriology in that institution.

From 1938 until 1941, I was a university fellow in pharmacology at the University of Chicago; and in 1941, received from that institution the degree of doctor of philosophy, with major work in pharmacology and minor work in physiology.

Shortly thereafter, I came to Washington as an assistant pharmacologist in the Division of Pharmacology of the United States Food and Drug Administration, where I served until December 1945.

During that period, I was promoted to the rank of pharmacologist; and when I left, due to the unfortunate loss of my chief, Dr. Herbert Calvery, I was then serving as Acting Chief of the Division of Pharmacology of the Food and Drug Administration.

In December 1945 I left Washington to accept appointment as lecturer in pharmacology and assistant dean of the school of pharmacy at the Medical College of Virginia; and since that time have held the various academic ranks through the grade of professor in pharmacology, served for a period as dean of the school of pharmacy, for a period as assistant president of the Medical College of Virginia, and I was appointed to my present post in July 1956.

During the time I was employed by the Food and Drug Administration, one of my duties was to consider and evaluate data for the purpose of assessing the safety of chemicals proposed for use in food.

Since going to Richmond, I have continued to do research on such chemicals. I have served as a consultant in this field to several industries.

I serve as a national consultant in pharmacology to the Surgeon General of the United States Air Force, and since 1950 have served as a member of the food protection committee of the National Research Council.

The history of this committee goes back approximately to late 1949 when various people concerned with this field in Government, in industry, and in the National Research Council, met to determine whether or not it would be feasible to establish a committee with the purpose of considering problems in this field; of working out general recommendations, where possible; of establishing or proclaiming such principles as it thought might exist with respect to this field; and of serving as an impartial adviser, either to industry or to Government, whichever might see fit to ask its advice in matters related to the use of chemicals in food.

That committee has published a number of documents in this field, and the one which I referred to earlier bears most directly on the problem which you have before you at this time.

Mr. Chairman, may I ask whether we have got my record up to date all right?

Mr. WILLIAMS. Oh, yes. That is fine.

I believe you said you were speaking as an individual and not on behalf of the group.

Dr. SMITH. Yes, sir. I have no authority to speak for the council whatsoever.

In a developing technological economy such as we have in this country, with a growing population and with the need for large quantities of manufactured and processed goods, it is inevitable that the scientists working in this field should wish to utilize some of the newer information which has become available, in preparing foods for the market.

In the case of so-called intentional chemical additives, that is, a chemical which is used in the manufacturing or formulation of a food for the purpose of imparting some desired quality to the food, such as a more pleasant taste, better keeping qualities, a texture more appealing to the consumer, or for other legitimate reasons, then the question immediately arises, granted that the reason for adding the chemical is a good reason, and speaking personally, I believe that a good reason, and only governing reason, should be some benefit which accrues to the consumer of the food, the problem immediately arises as to how best to determine whether or not a particular use of a chemical will be safe from the public health point of view.

It should be said, probably, at this point, that although the tests and procedures and the methods which are available to us at this time can establish with a reasonable degree of certainty that no harm to the public will result from a given use of a food additive, it is not possible in the present state of our knowledge to establish with complete certainty the absolute harmlessness of any chemical whatsoever.

In all of this, it is necessary to consider not what would happen under the most strained circumstances, but what is apt to happen under all likely patterns of use and consumption of the chemical in question.

The first thing, then, that one must do is to establish what the possible intake of such a chemical compound might be under all likely patterns of consumption.

The second thing one must do is to determine, by means of procedures which I shall attempt to describe in a few moments, just what changes this particular chemical is capable of bringing about when it is administered to experimental animals, and to determine just what quantities are necessary to bring these changes into play.

Then, with the knowledge, on the one hand, of the amount a human is likely to ingest, and then with the knowledge, on the other hand, of what this chemical is capable of doing to animal organisms when it is given to them, and by applying certain factors known as margins of safety, it is possible to conclude with reasonable certainty—and I am afraid I must admit here that we are dealing, Mr. Chairman, with what is described as an educated guess—but we can state with reasonable certainty whether or not the proposed use of this chemical is likely to be safe.

It would be helpful at this point, I think, to state that there is no substance of which the witness is aware, including water, vitamin C, and common table salt, which will not produce serious illness when ingested to an unreasonable extent.

For instance, if animals are fed as much as 25 percent of vitamin C or ordinary table salt in a diet, according to the work of Professor Frazer of the University of Birmingham in England, the effect is lethal.

Mr. WILLIAMS. That would have to be over a period of time, would it not?

Dr. SMITH. A relatively short period, if as much as 25 percent in a diet consisted of salt.

So it is not a matter of dealing in black and white, of saying whether a thing is poisonous or it is nonpoisonous. It is a matter of determining, as best we can, with the tools we have at hand, whether a given use is apt to be safe.

In order to determine this, there are a number of things which must be at hand, a number of different kinds of data.

The first thing that is necessary is to be able to determine, through reasonably simple chemical procedures, just how much of a given material is in a particular food. It is also necessary to be able to measure amounts of a proposed chemical additive in the animal body, in order that one can determine what happens to the chemical additive when it is given to the animal, when it is fed to an animal.

In other words, before you can proceed with the more complicated testing with any reasonable degree of assurance, this basic tool is needed: a chemical method of determining with reasonable certainty just how much of the material is present under experimental conditions.

There are other things which must be known about the chemical, substances which are chemical in nature, and one of them is stability of the material, whether or not it changes to any extent or whether it

is changed to any extent when it is added to the food, through reaction with other components of the food or through any of the processing procedures, such as heating which might take place in food processing.

It is also necessary to know whether the material, when added to food, will affect the nutritive value of that food. And this can be established either by feeding treated food to animals, or by feeding the material itself, to determine whether it interferes in any way with the utilization of foodstuffs taken in by the animal during the course of the experiment.

The next step is to measure the toxicity of the proposed compound; and here I might define "toxicity," which is the capacity of a chemical substance to produce injury.

As has been pointed out, all ordinary substances have that capacity in some degree. It is necessary at this point, in trying to assess the safety of a proposed chemical for use, to determine to what degree the proposed substance has the capacity to produce injury.

Generally, this is done by administering the substance in question to animals, in several different types of experiments which are generally classified according to the duration of the exposure of the anmial to the compound in question.

The test which is generally conducted first is called an acute toxicity test which attempts to measure the injurious effects, if any, brought about in animals by a single dose, a single dose, a single amount, a single treatment, of the compound under study.

So far as intentional additives in foods are concerned, most of the chemicals to be studied can be expected to be fairly nontoxic. They are not going to be very poisonous things, so to speak.

The chemical manufacturer seeking new and useful compounds in this field quite readily rejects from consideration any compound which is obviously so toxic, when taken in a single dose, that it might cause injury.

Mr. WILLIAMS. Doctor, at this point I think it would be well to distinguish between the intentional additive and the incidental.

Dr. SMITH. All right, sir.

In the early days of the Food Protection Committee, it was found desirable to standardize, at least for the committee's own thinking, the terminology involved. In dealing with food additives, you are dealing largely with two different groups now. One is the group of intentional food additives, which is added directly with knowledge that it will be in the final product, with the idea that it will impart some desirable or useful quality to the food product. That is the intentional food additive.

The incidental food additive is a substance which appears in the final product as it is received by the consumer, not intentionally, but incidental to its use somewhere back along the line of food production, such as a pesticide which is necessary in order to produce a food crop.

The farmer does not want a residue on his material as it reaches the consumer, but in many cases it is inevitable. So the residue there is incidental to its necessary use back in the production of the crop in the field.

Of course, there are other types of incidental food additives. Materials which get into food incidental to their use in food packaging

might be regarded as incidental additives. They are used, not because they are wanted in the final food product, but for some purpose thought valuable in packaging, but some quantity of the chemical may incidentally find its way into the food.

Mr. Chairman, are those definitions fairly clear, or would like to ask me a question about it?

Mr. WILLIAMS. I think I understand them. I hope and I presume the other members of the subcommittee do. If they have questions, they will ask them.

Mr. HARRIS. Could I ask a question? It may not be the appropriate time or place, but would you describe the difference, if there is a difference, between a food additive and chemical additive, or have you just done that?

Dr. SMITH. No, sir, I have not.

When I said chemical additive and food additive, I am afraid I have been using the two terms interchangeably, sir. All of these food additives are necessary chemical. Everything is chemical.

In general, they are referred to as food additives. The way one finds them and deals with them is as chemicals, so what they are are chemical additives used in foods. Whether I said "chemical additive" or "food additive," I mean the same thing, sir.

Mr. HARRIS. I am glad to have that clarification, because I notice you have been using the term "food additive" and the term "chemical additive," and yesterday when Mr. Dunn was before the committee, he was very insistent on changing the term proposed in H. R. 6747, "chemical additives," to "food additives."

If it means the same thing, I do not know why it would make any difference.

Mr. WILLIAMS. I think you find, do you not, Doctor, that the term "food additives" is a public relations term to get around the term "chemical additives"?

Dr. SMITH. That is true, because some people attach an undesirable connotation, which is emotional rather than realistic, to the word "chemical." Everything they take in, every food, everything they drink, everything that surrounds them, is chemical. But it just has some undesirable connotation to some people, and unfortunately it has been exploited by people who like excitement at other people's expense from time to time.

To go back, then, once one has found out the single-dose toxicity, the so-called acute toxicity of a chemical, which more often than not is not a matter of concern with intentional food additives, he learns enough about the material to go on to the next step, and he moves on to the thing which is generally governing in determining the safety of food additives, and that is whether or not they produce some deleterious effect when they are ingested over a period of time.

These two things, single-dose toxicity and the other more extended tests, are entirely different things. I think it is well for the committee to understand that one cannot simply give a single dose of a material and then conclude from the results of that test that the material is safe for use in humans, because it is quite possible for material to produce no evident deletereous effect in a single dose or acute experiment, and then when it is fed to animals over a period of time, to produce highly dangerous reactions, including death.

So that the next step, utilizing the knowledge gained in the acute toxicity test, is to feed the material, usually in a diet, to some short-lived animals, such as a rat most usually, for a period of approximately 10 percent of the life span of the animal. And in the case of the mouse or the rat, this would be approximately 2 to 3 months.

In this test, generally called a subacute feeding test, one can sometimes determine in a hurry that here is a material which is quite possibly too toxic to be useful in food.

On the other hand, the material may emerge from this so-called subacute test with flying colors, but this would not mean that the material was safe for use in food.

Usually at this point, if the material, the proposed food additive, looks as though it will be safe for use, a longer term feeding test is initiated, and here we get into a rather difficult problem because it involves feeding animals over essentially their average life span. In the rat that is approximately 2 years, and this is a long period of time to wait in arriving at what is an important decision, both from the standpoint of the company which seeks to put a useful, usable, safe product on the market, and from the standpoint of the prospective consumer.

It may be that this 2-year feeding test, feeding of material over the greater part of a life span of a short-lived animal, is either too rigid, unnecessarily rigid, or, on the other hand, it may be that it is not rigid enough.

The point I would make here is that, so far as the witness is aware, experience to date has not provided a more rational alternative. In other words, we are confident that after studying the material in one animal species for the greater part of its life span, and for shorter periods in other animals, to get some idea of variation among species, that we can assess with reasonable certainty the safety of its use under particular circumstances.

By and large, we do not have any procedure we can safely say will take the place of this extended feeding test—that is, for the greater part of the life span in most instances.

In some cases, where we have been fortunate enough to know a good deal about the chemistry of proposed food additives, it has been possible to demonstrate their safety with purely chemical procedures and biochemical procedures, without carrying out the life-span investigation.

But in the present state of our knowledge, we cannot expect any time soon to be able to assess the safety of these materials with certainty, in a large majority of cases, without resorting to these life-span tests.

We resort, then, to the single-dose or acute-toxicity test, or slightly elongated version which feeds the animal about 10 percent of its life span, and then finally to this experiment in which the animal is studied over the greater part of his entire life span.

In all of these tests, the animal is observed in every way known to be useful to determine whether there have been any adverse effects from the treatment with the proposed food additive.

These involve tests of functions of organs. They involve observation of food intake; is the animal eating as it should? It involves observations of weight gain, do the animals gain weight normally?

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It involves general observation of general appearance of the animal. And it involves biochemical tests of organ function.

And finally, it involves sacrifice of the animal and the examination of its tissues, both as to gross appearance to the trained eye of the pathologist, and as to the appearance of the tissues when sliced into thin sections and examined under the microscope.

Another thing which might be said about each one of these three types of toxicity tests is that it is important to use several species of animals in each instance in order to determine whether there is a reasonably uniform response to the proposed additive among species.

That is useful in this way: If a chemical is found to be one degree of toxicity, say, in a rat, and about the same in a mouse, and essentially the same in a dog, that is three species, one of them a nonrodent species, then one feels that he can translate that information over to man with reasonable certainty, because if these three species all react pretty much the same, it is a reasonable assumption that man will.

But if there is a wide variation among these several species in the response to this proposed chemical additive, then one has to proceed with a great deal of caution in making assumptions as to whether the animal data will be applicable to man. And generally in those cases, one assumes that man is at least as susceptible as the most susceptible animal species, and then applies a large arbitrary safety factor in order to be sure that the proposed use will be safe.

In general, in relation to these investigations, one point which the witness has heard made over and over again in recent years in connection with such studies is that, while it is helpful to have written down on paper for guidance the advice of scientists who are working in this field, it would not be helpful if there were a set of uniform procedures which were prescribed and obligatory, because this would serve effectively to slow down progress in the development of more effective procedures and methods.

It is felt that the scientist, working in this field, utilizing his training and experience, should be able to design for each proposed additive the research program which will be most likely to yield helpful information, and that there should be no hampering of his exercise of his wits and experience in deciding just what is best to do to demonstrate the safety of the proposed use of a particular additive.

One hears on the one hand a cry for uniform procedures that can be easily interpreted; and then immediately they are written down as advice, one hears on the other hand cries as to being put into straitjackets.

The fact of the matter is that there is no easy way to solve these problems, but we are dealing with, always, matters that we do not entirely understand, and if we are to progress to the point where we have more certain, easier and more economic methods, then nothing must be done to slow down the research into the development of new methods and new procedures.

I know this has been a rambling discussion of doubtful value to you gentlemen, and in truth I must admit that Dr. Arnold Lehman, who sits behind me on my left, knows more about this than I do, and I would be very happy to try to answer any questions you might have, if I may.

Mr. WILLIAMS. Thank you very much, Doctor.

Mr. Dies, do you have any questions?

Mr. DIES. Doctor, you have outlined the procedure for testing these additives, and you quite frankly admitted that they can only approach reasonable certainty. There are always elements of doubt, and probably always will be.

But what is known—let us assume that an additive has been tested and found, insofar as you are able to find, that it is reasonably safe—what about its cumulative effect, and especially its effect as it is used in association with other chemicals?

If, for instance, in the daily diet of a man he gets one chemical from one food, another chemical from another food, what is the cumulative effect of all the ingestion of these chemicals so far as the scientists have been able to ascertain?

Dr. SMITH. The cumulative effect, sir, of any given additive, or any proposed food additive, is studied as a part of these procedures I have mentioned in the more prolonged feeding tests, the long-term tests. That is, any cumulative effect a single proposed additive may have is usually made clearly evident in the long-term feeding tests.

As to the cumulative effect which I think you are referring to, of adding chemical after chemical of similar nature, I do not know the answer to that problem, except that the regulatory authorities are well aware of the materials that are used as a rule, and they can take that matter into consideration in deciding whether or not a particular use of a food additive is safe.

There again, sir, I think there has to be judgment.

Now, as to the statement of mine that we can determine these things with reasonable certainty, I would say that, so far as I am aware, there is not any substance that has passed all these tests with a clean bill of health which has been demonstrated later to be harmful to the public.

Mr. DIES. You think, in other words, that the record demonstrates that these tests are fairly accurate? That over a period of years, the experience with them has shown that they are fairly accurate?

Dr. SMITH. I would say, yes, sir. I would say that if the procedures generally employed are used by people who know what they are doing, then the only way I know how to express it is, I have no fear on the part of my children, sir. That is a test I always apply.

Mr. DIES. I want to ask you a question. I know you perhaps are not familiar with this bill, nor do I want to ask you about the mechanics of the bill, but rather, as laying the predicate for the next question.

This bill has the same language as it did in 1956. I was a member of this subcommittee and heard all of the evidence. I do not know whether any other member here was on this subcommittee then or not.

But, like that bill, this bill says—

> The term "chemical additive" means, except as otherwise provided in subparagraph (2), any substance the intended use of which results or may result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * *

It then hinges on this statement:

> if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm * * *.

Now we have the same question which was asked in 1956 about that standard being vague, somewhat indefinite, and I wanted to ask you, it may be the only thing they can work out, but I wanted to ask you this: There are, I assume, many additives that have been, of course, tested many times. Is that true?

Dr. SMITH. Yes.

Mr. DIES. And those additives are generally recognized among the scientists as being safe?

Dr. SMITH. I would say, sir, assuming that they have been through the general studies that I have indicated earlier here today, I would say they would be generally recognized as safe by the scientists who have a close connection with this type of scientific consideration.

There are so many related scientific fields and they are all so highly specialized, that if a man were a highly qualified chemist, for instance, and he had had no experience in evaluating these factors, I would have little faith in what he concluded from the data.

But I would say that these chemicals are regarded as safe by the scientists who have been closely associated with this field. That is, those that have been studied according to the recommended procedures.

Mr. DIES. Well, the question——

Dr. SMITH. Or some modification of them.

Mr. WILLIAMS. Would the gentleman yield?

Mr. DIES. Yes.

Mr. WILLIAMS. Under this definition as appears in the bill, it appears to me that the chemical is not considered to be an additive unless it is harmful. The definition of it is that——

Mr. DIES. That is true.

Mr. WILLIAMS (continuing). If it is not harmful, it is not an additive, under the definition of this bill.

Mr. DIES. Well, yes. But, of course, it says "if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate," and so on and so forth, and that puts the burden upon the food manufacturers to determine in the first instance whether or not the additive that he proposes to use or is using has not been generally recognized by experts as being harmful.

I do not know, but I thought maybe since you were in this field, and acquainted with the people in this field, you might throw a little light on how that would operate, whether you think there are enough standards there, criteria, to have any reasonable certainty, or not.

Suppose I am a manufacturer, and I know that it is incumbent upon me now, if I am going to use this additive, it must be one that is not generally recognized as harmful. Where would I go to get that information? Is that fairly available to the food manufacturers, that information?

Dr. SMITH. One thing that a man could do is, he could come to the Food and Drug Administration and ask them. They have about as complete files as any organization in the world, and have always been very cooperative.

Another thing that the manufacturer could do is to avail himself of any one of a number of capable private consultants who make a living engaging in this type of work.

In addition, there are people in the universities who, because they believe this is an important field, engage themselves as consultants for manufacturers in dealing with these problems.

I would say that there would be no difficulty connected with the manufacturer getting advice that he needs.

I would say there are a number of consultants who would like to be asked for more advice, sir.

Mr. DIES. And you think that that information would be available, and there would be no vagueness in determining who are the experts in the field; that that, too, could be determined?

Dr. SMITH. Sir, I believe that language—I am not a lawyer, and I hope I may answer with a question mark at the end of what I say. I believe that language is generally similar to that which was used in the "new drug" provision of the act.

Mr. DIES. That is true.

Dr. SMITH. And it is my impression it has worked out very satisfactorily there, sir.

Mr. DIES. I understand that it has. I do not know that for any certainty, but I have heard that it has worked well on that.

There is just one other thing I want to ask you about and I want to take up.

Here on the question of the functional use, there has been a great dispute about that. Generally, the food manufacturers agree that someone ought to determine whether it is safe or not. The welfare of the consumer is the primary consideration. But they take exception to giving any power to the Food and Drug Administration to determine whether the functional use of it is justified, and so on and so forth.

What do you think about that? For instance, a manufacturer proposes to use it, not because it adds anything to the nutritional value of the food, but simply so that he can sell it, so that it will have a better appeal to them, such as orange juice, for instance.

We had that dispute before the committee, using coal tar to make an orange look attractive, because it is contended people would not buy them unless they are red.

Do you have anything—I am not asking you from the standpoint of the law involved in it—but do you have anything to contribute to that?

Dr. SMITH. It would be out of my field, sir, but as a private citizen, I would go back to the fact that we can only demonstrate this safety with reasonable certainty, and in those circumstances I would feel that there should be a demonstration of usefulness, some benefit conferred on the consumer.

If I could tell whether it is safe as easily as I could tell the white from the red on this towel, that would be one thing. But we cannot do that with additives. So I would take a conservative point of view as a citizen and say I should think there should be a definite benefit accrue to the consumer.

Mr. DIES. That is one of the burdens which the manufacturer ought to assume, to show not only it is safe, but also it has a functional use?

Dr. SMITH. I would not say that it should or should not be the burden of the manufacturer, sir. It is a highly controversial field, and

if I discuss it much more I am going to destroy my usefulness as a scientist in this field. [Laughter.]

Mr. DIES. Well, I am not trying to—I thought perhaps from the viewpoint of the scientist, you could give us your views.

Dr. SMITH. Well, the scientific side of it is that we can only assure you of safety with a reasonable degree of certainty, and for that reason it does no harm, I think, to require that there be some ascertainable benefit conferred upon the public in the matter.

If it makes more food freely available, or even if it makes it more acceptable to the housewife so she wants it, it seems to me that is a benefit.

I would not argue too much about the nature of the benefit. I do not think you can pin it down. I think you have to be reasonable.

But I do think you would have to be able to see some kind of benefit that the public gets in return for only having reasonable certainty.

Mr. DIES. That is all I wished to ask.

Mr. WILLIAMS. Mr. Heselton, do you have any questions?

Mr. HESELTON. Mr. Chairman, I regret I did not hear all of Dr. Smith's statement, but have you commented on the testimony of Mr. Dunn—were you present yesterday to hear him testify?

Dr. SMITH. No, sir; I was not aware at all of this hearing until Friday, and I just got here this morning at 1 o'clock.

Mr. HESELTON. You have not had a chance to read his statement?

Dr. SMITH. No, sir.

Mr. HESELTON. I would think, in view of your position, it might be useful if you had the time between now and, I gather, September, to comment on Mr. Dunn's statement in any detail you wish.

I would suggest also that you comment on the statements that have been filed with the committee by the Department of Health, Education, and Welfare, and the Food and Drug Administration.

Would you be willing to undertake that and make it a supplement to your statement? You do not have to do it today or tomorrow.

Mr. DIES. Would the gentleman yield?

Mr. HESELTON. Surely.

Mr. DIES. The gentleman was not here, I believe, at the beginning of the testimony. As I understood it, this witness was asked to come here and give us solely the method by which the tests, from a scientific standpoint, were carried on, and it might be embarrassing for him to get into the question of the bills and testify on it.

Mr. HESELTON. Of course, you do not have to comment on what you do not care to comment on, and my suggestion has not harmed you or anybody else.

Dr. SMITH. I should appreciate it if the committee would allow me to restrict myself to the scientific side of this matter. The things I just said, I said purely as a citizen. I represent no one.

Mr. HESELTON. I understand that.

Dr. SMITH. Of course, the other gentlemen represent very substantial people who have given a good deal of thought as to the way this thing should be handled, which I have not.

Mr. HESELTON. I thought you were discussing the propriety of certain definitions. I may be mistaken about that.

Dr. SMITH. No, sir. I merely tried to answer, sir, the question put to me.

Mr. HESELTON. That is probably what I did not hear.

Dr. SMITH. I did not volunteer that.

Mr. HESELTON. You did not volunteer it.

Mr. WILLIAMS. Will the gentleman yield?

Mr. HESELTON. Yes.

Mr. DIES. I tried to make it clear I was not asking him from the standpoint of whether this was a proper definition or not. As a scientist, I was trying to ascertain who the experts were, and whether they were generally known, and so on and so forth.

Mr. HESELTON. Let us leave it this way. You do not have to file anything.

Dr. SMITH. Thank you.

Mr. HESELTON. If you do care to say something about it, perhaps you might let me know about it. There might be something of value.

There was one phase of your statement I did hear which perhaps I misunderstood, or at least I would like to be a little bit clearer on, and that was your suggestion that there might be danger from too much rigidity as to these various tests that competent scientists might apply.

I can thoroughly understand why you or any other competent person in the field would hope to get away from that. But I think it poses a real problem to this committee in terms of devising, if possible, the wisest course by which those who are charged with determining the propriety of certain additives, whether they are chemical or food additives or whatever anybody wants to call them, can work it out.

You either have to have something of a general nature which will apply to everybody, or else you open the door wide, it seems to me, and say any competent scientist can work in any way he wants to and come up with any result, and there is no way to test whether it is correct or not.

How are you going to be able to protect the people who use the food if you do not lay down some guidelines which must be followed, so that there can be a test made of the conclusions, not only by the Department which has certain responsibilities, but eventually, if you get into the courts, so that the court itself and the attorneys and the experts engaged in the case may know where you start off and where you are ending?

Dr. SMITH. It seems to me, sir, that the only way to handle that would be to leave it to the administrative agency to determine whether or not a given material has been demonstrated to be safe, whether a given use of a material has been demonstrated to be safe.

Mr. O'HARA. Will the gentleman yield at that point?

Mr. HESELTON. Surely.

Mr. O'HARA. Doctor, we have a great responsibility placed in these bills on the administrator, who is a layman who probably does not know much more about the scientific side than I do.

He is going to be charged with the responsibility of making the decision. True, he is going to accept the advice of people he has in his own department, either rightly or wrongly, which may create a very hazardous problem for some food company or some chemical additive company as to what review they are going to have over maybe a prejudiced adviser to the Administrator.

How are we going to protect both the public and the individuals involved?

Dr. SMITH. Actually, sir, it has been my personal experience that that responsibility slides from the Administrator to the scientist in about half a second, and it rests right there until the scientists are satisfied they have their answer, and then the administrators generally act on the basis of what they recommend.

We are fortunate in this country, it seems to me, that the people dealing with these problems have more experience, to the best of my knowledge and belief, than those in any other laboratory in the world.

Mr. O'HARA. Doctor, I have the greatest respect in the world for scientists. When they become expert witnesses, they are human beings. They are subject to all the frailties and prejudices that every other human being may have.

Is not that situation true?

Dr. SMITH. Well, this one certainly is.

Mr. O'HARA. That is all I have, Mr. Chairman.

Mr. HESELTON. Doctor, in the report of the Department of Health, Education, and Welfare on this bill, and perhaps others, there is a sentence. After referring to the fact the bill would furnish an adequate pretesting requirement, this is the following:

> It would permit this department on its own initiative or at the request of any interested person to issue a regulation announcing the conditions under which an additive may be used safely.

And then one further sentence:

> The regulation could issue only on the basis of scientific evidence that the proposed use would be safe.

As Mr. O'Hara suggests, perhaps the day will come when it will happen, but you do not ordinarily find a competent scientist drafting these regulations.

I can understand fully why scientists should be given the greatest latitude in terms of developing new tests, and which may be more satisfactory.

On the other hand, our problem in writing any law, if any law is needed, is to lay down some standards which can be understood by the people who are charged with the responsibility of administering the law, and which can be tested, presumably, by the courts.

What I am trying to get at, if I can, for the record, is this: You suggest, if I understand it correctly, that we should guard against laying down anything too definite, rules which might handicap the scientists or competent scientific personnel, in this field, in view of the enormous number of additives that have come into being, so that they can search around and perhaps develop better means of testing the additives.

On the other hand, you must have, it seems to me, some standards written that can be understood by at least an intelligent layman, and we have very few scientists on any courts. I assume we will have some testimony from one of the ablest judges in the United States, as we have had previously, with reference to certain standards.

Do you visualize that this bill should be written in terms of the ordinary work of the scientist, or do you think there should be some combination of allowing the most latitude to the scientists, but at the same time confining those scientists who are engaged, for instance, by a food manufacturing company, to certain areas in which they must follow a standard of some kind which can be tested itself as to the results?

Dr. SMITH. If you will excuse me, sir, from commenting on the provisions of these bills which are controversial, I should like to simply say that there is no difficulty whatsoever for a food manufacturer to go out and get competent help to help him through this problem, right on down the line.

And if I were in the food business tomorrow morning, I cannot say there would be any difficulty about knowing what I should do. If I did not know myself, there are competent counsel and competent scientific advisers available.

The National Research Council has described—in general, it is true, but nevertheless it has described—the type of thing that it thinks is necessary. It is not too dissimilar from exactly what the Government laboratories publish.

There will shortly be an international document on this subject, which I would not expect to be vastly different.

And I can see no difficulty in leaving the determination as to how to proceed in the laboratory to gather this data, to the scientist. To my mind, it would create an awful situation if you sought to write these procedures into law or into regulations.

Mr. HESELTON. I do not want to pursue it too far with you, Doctor, but I think a real problem is posed in terms of the suggestion you made, and I can see there may be a great deal of merit to it; I mean if you deal with it purely as a scientific or technical matter.

But either you are going to have some type of satisfactory legislation to implement what I suppose everybody wants, irrespective of their direct interest in it, and that is safe food for the public, or you have to throw your hands up and say it is beyond the capacity of ordinary individuals to work out a law and administer it. Then you must conclude that this is a field in which the ordinary layman is incompetent, and we simply have to leave it to the scientists.

I mean no reflection on anyone when I make this statement. I happen to be a lawyer, although I have not practiced for a long while actively. A good many of the members of this committee are lawyers. We all know that a lawyer is not worth his salt if he cannot take a given set of facts and try to fit them legally into your client's purposes and objectives.

I do not say that lawyers necessarily are any different from scientists, or scientists are any different from lawyers. But if "X" company wants to engage a competent scientist to prove that their product is safe for human consumption, I suspect that there is a human tendency on the part of the scientist to find ways to justify a conclusion that it is safe.

Do you think that is possible?

Dr. SMITH. It has not been my experience, sir, that any of the people, even of the people who are directly in the business of consulting and who might be tempted, you might say, I have never had the experience of seeing any one of them reacting in that fashion, to the best of my knowledge and belief.

Mr. HESELTON. You know of cases which have been carried through the courts in which a manufacturer has accepted the burden of proof that his product is safe, and where the Department has insisted that it is not safe. Do you not know of those cases?

Dr. SMITH. There is always room for honest differences of opinion.

Mr. HESELTON. That is so.

Dr. SMITH. We are not dealing with certainties; and even if you prescribed the procedures, you would not eliminate the situation to which you refer. You still have differences of opinion, depending on background point of view and experience, and there is no easy way out that I know of.

Mr. HESELTON. That is all.

Mr. WILLIAMS. Mr. O'Brien?

Mr. O'BRIEN. Doctor, you said there is no possible way to determine the absolute harmlessness of any chemical whatsoever. I am interested in these tests on animals. Is it not true that some additives might be perfectly all right for 80 percent or 90 percent of the consumers, and they might be very harmful to the other 10 or 20 percent?

I am thinking of the old saying, "One man's meat is another man's poison."

My question is this: Would that pattern reveal itself in the tests of these animals? In other words, would a certain percentage, perhaps a great majority of the animals, consume the foods or additives without any harm, and then would there be a smaller percentage which would be harmed greatly by them?

Dr. SMITH. There have been instances in the drug field where small numbers of individuals react in a highly abnormal fashion to a thing which does not hurt other people at all. It has been a pretty scarce occurrence, to the best of my knowledge and belief.

In all of those things, I think it is advisable, if possible, to go on and do some experiments in the human after the animal work has been done, but even there, it would not be possible to do a controlled experiment in very many humans.

I think the likelihood of something happening such as you envision is very small. But I could not say it would not happen, sir.

Mr. O'BRIEN. Thank you.

That is all.

Mr. WILLIAMS. Mr. Carrigg?

Mr. CARRIGG. Doctor, carrying Mr. O'Brien's thought just a little bit further, as I understand it all of us have certain idiosyncrasies or perhaps certain allergies toward different drugs, and I am wondering whether or not, according to some of the testimony that you have already given, when you are testing these additives on animals, for instance rats, you said it was always desirable to know what is the chemical content of the rat itself, before you begin this test.

Dr. SMITH. We want to be able to determine what happens to this compound in the animal's body after it is eaten, what it does to the chemical processes in the animal, and what the animal does to break down the additive.

In other words, what we call the metabolism of the drug, whether or not it is absorbed, whether or not it is stored, whether it is modified in the body, whether or not it is modified by the ordinary chemical processes that go on, and so on.

Mr. CARRIGG. Is that a rather difficult process in your checking or testing these chemical additives?

Dr. SMITH. Yes; in some instances you cannot get all that information, but so far as I know, everyone endeavors to get as much of it as can be had with the tools that are available for that particular problem.

Mr. CARRIGG. Is that one of the reasons why you feel we should not be too rigid in writing up rules and regulations concerning the way the scientists should go at this problem?

Dr. SMITH. Well, my primary reason is, if you do that, you will set them in a rigid mold so that they will not be seeking and searching the way they should for the best way to do it. They will do it the way it was written in the law ten years ago. I think it is a very easy way to stultify progress.

Mr. CARRIGG. Personally, Doctor, I hope we will not try to impose our will upon the will of the scientist. I believe these men are dedicated men in most instances.

Dr. SMITH. Another difficult point is that if you called together a hundred people who are scientists, if they were not very well oriented in this field, I doubt if you could get them to agree to advise you in any one way.

So how you decide which procedures to put in your legislation, I do not know, although there is rather general agreement, I would say, among people working closely in this field, that this is the basic group of procedures, and that those working in the field should be free to use their training and experience to try to develop better ways of accomplishing the same thing if they can do it.

Mr. CARRIGG. Thank you, Doctor.

Mr. DIES (presiding). Mr. Loser?

Mr. LOSER. Nothing at all.

Mr. DIES. Mr. Bush?

Mr. BUSH. Doctor, when or how long has it been since we started to use chemical additives in foods?

Dr. SMITH. It has been a long time, sir, but the usefulness, the broad use, has grown up with the changing nature of our country, I think. It used to be that the eating unit was one family living on one farm. But when you get to shipping canned, preserved, frozen materials all over the country, and in some cases across the world, then very real reasons enter for using chemicals in food.

You get to the point where, in some instances, they are indispensable. For instance, in some areas, it is just not possible to keep an adequate supply of fat without using a preservative known as antioxidant in those fats, and to those countries the use of antioxidants is just as important as the use of insecticides to the American farmer.

So, as we have grown to rely more and more on food, the highly processed food that is shipped for long distances, food that is prepared for many tastes, we have come to use more and more additives.

But, so far as I am personally aware, I do not believe there has been any instance of any real harm being done. But the reason we have not had it is because there has been an extremely effective group of people watching this since 1906.

Mr. BUSH. Thank you, Doctor.

That is all.

Mr. WILLIAMS. (presiding). Doctor, I have one or two questions I would like to ask.

This may not sound like a relevant question, but I think it is more or less pertinent.

At what point would you say that a component used in the preparation of food ceases to be an ingredient and becomes an additive? Do you understand what I am driving at?

Dr. SMITH. Yes. It is a highly technical question, Mr. Chairman. I would hate to give a horseback opinion on that one.

Mr. WILLIAMS. Well, I am thinking of all the things I can mention as examples.

The use of junket tablets in the making of ice cream. Some think you can make the ice cream without them or with them. As I understand, it makes it more or less smooth if it is used to make ice cream.

Let us get down to flavoring used in ice cream. Is that considered an additive?

Dr. SMITH. As I understand it, there are substances used in ice cream to produce a smoother texture, which is currently highly desirable because people like to buy it that way, and they are generally regarded as additives, I believe.

Mr. WILLIAMS. Well, let us take the question of the flavoring that is used, say, in the making of ice cream. It is utterly impossible to make chocolate ice cream without chocolate flavor. Is the flavoring considered an additive?

Dr. SMITH. I would not call chocolate an additive in chocolate ice cream, no, sir.

Mr. WILLIAMS. You can make the ice cream without the chocolate, but it is not chocolate ice cream.

Dr. SMITH. That is right. [Laughter.]

Mr. WILLIAMS. Or the use of chili powder, say, in making chili. Is that an additive? Chili would hardly be chili without the flavoring.

Dr. SMITH. I am afraid you have got me out of my field of capabilities, sir. I have been out of it a long time, but I am way out of it now.

Mr. HESELTON. Will the chairman yield?

Is oleomargarine a food or an additive?

Dr. SMITH. It depends on what State you come from. [Laughter.]

Mr. WILLIAMS. Doctor, are there any chemicals which, used separately, are harmless, but which create a problem when used together?

Dr. SMITH. It would arise primarly where there developed the use of a large number of related compounds where theoretically they would be acting more or less the same way, and all of a sudden you would get beyond your tolerance.

I do not know how you would define the danger or define the way of attacking it at all, except by relying on the fact that it is generally recognized among scientists that such things can happen, and should be watched for.

You could not possibly test all food additives in conjunction with all other food additives. It would do things economically worse than a few poisons in the food supply.

Mr. WILLIAMS. Well, take a hypothetical case of tomatoes, where additive A is used as a preservative for tomatoes. Taken by itself or with the tomatoes, it is perfectly harmless.

Additive B, we will say, is used in preserving corn, and it, taken by itself, is perfectly harmless.

However, when the corn and the tomatoes are mixed, and additive A mixes with additive B, it becomes, to some extent, a poison. Is that problem prevalent to any extent?

Dr. SMITH. I would say it would be an extremely unlikely thing. I would not like to sit here and say it is impossible, because anything is possible. But I would not fret over it for a minute, sir.

Mr. WILLIAMS. You do not think it is important enough to bother with?

Dr. SMITH. I think where there is a real possibility, it would be taken into consideration by the people responsible, and I know no general way of guaranteeing that it will never happen. It is a theoretical danger I would not know how to deal with.

Mr. WILLIAMS. Of course, the case that comes to mind, and it is far removed from food, anyhow, but it nevertheless occurred, was when Massengill mixed alcohol and sulfanilamide and attempted to make an elixir with an alcohol base.

Dr. SMITH. Yes, sir.

Mr. WILLIAMS. Each of the ingredients, I assume, were relatively harmless separately, and when taken together——

Dr. SMITH. No. Diethylene glycol was the solvent, the poison in the case.

Mr. WILLIAMS. That was what brought up the question in my mind.

Dr. SMITH. What happened there was that diethylene glycol had been studied only in so-called acute toxicity tests. If that compound had been observed over a period of time in animals as it was observed after these people died, it would become immediately apparent that it should not have been given over a period of time to humans.

Mr. WILLIAMS. Doctor, getting back to a practical example with which most of us are familiar, take the case of watermelons. If watermelons are overfertilized with certain types of fertilizer, they change the taste of that watermelon considerably. A watermelon which has been highly fertilized, as all of us know, tastes quite differently from a watermelon where a minimum amount of fertilizer has been used.

Does that type of thing point up any problem as an incidental additive?

Dr. SMITH. I would say that would be a built-in safety factor, sir.

Mr. WILLIAMS. How do you mean that?

Dr. SMITH. I mean that the man who does not like his flavor tampered with is probably not going to eat those watermelons, and the farmer will probably use something else.

Mr. WILLIAMS. That is true. Could the chemical reaction brought about through the use of that type fertilizer be considered as an incidental additive? Would that come under your definition of an incidental additive that you told us about some time ago?

Dr. SMITH. Excuse me, sir. I say it would be going right far. Actually, that is a practical matter, and there have been certain agricultural fungicides that were very helpful in preserving tomatoes, for instance, but because they adversely affected the flavor, they just were discarded in a hurry, and there may be some way that the farmer should be safeguarded from economic losses there.

But I would not say it had any relation to health, because these compounds had all been studied very adequately with regard to their safety for ingestion.

Mr. WILLIAMS. Some of the bills which are before the subcommittee now make specific mention of cancer-causing characteristics of various chemical additives. Would you care to discuss that for a moment?

Dr. SMITH. I am not an expert in that field, sir, and it is a field to which a great deal of study is being given at this time.

My personal feeling is that the tests which are done almost routinely give reasonable assurance that any potent carcinogen would be picked

up. There are people studying this problem now, and it may be they will have recommendations as to additional things that ought to be done, I do not know.

But I personally do not feel that the problem is acute enough to cause great worry at this particular moment, because it is receiving concentrated attention, and I feel sure there will be a greater degree of agreement on this thing as soon as these groups can complete their present studies and recommendations.

It is just a matter of the people who know most about the thing getting together and working out what they think is right. For the meanwhile, I think the possibility of any cancer hazard is remote enough that we should not worry too much about it.

Mr. WILLIAMS. Doctor, does it follow, that if a chemical injected into the skin should cause cancer, that that chemical taken internally would likewise cause cancer?

Dr. SMITH. No, sir.

Mr. WILLIAMS. That does not necesarily follow?

Dr. SMITH. No, sir. You can take sugar, inject it beneath a rat's skin, and produce a sarcoma.

Mr. WILLIAMS. Of course, we all have been very much interested in reading, during the past 2 or 3 years, reports on the relationship between cigarette smoking and cancer. I am not going to ask you a question on that subject. But we have read quite a number of statistics which would show that the greater proportion of cigarette smokers contact lung cancer, and statistics also on the other side, for that matter.

With respect to the scientific tests which are generally conducted to determine whether an additive is safe or not, do you generally take into consideration also—statistical proof of that nature with respect to an additive before determining finally whether it is safe or not?

Dr. SMITH. In designing experiments, it is important to so construct the experiment that the data obtained will be susceptible of statistical analysis so that the investigator can determine, within known limits, whether or not his findings are due to chance, or due to the treatment he gave the animals, yes, sir. That is the usual procedure.

Mr. WILLIAMS. Mr. Heselton, I believe, has a question.

Mr. HESELTON. Doctor, I am afraid that as far as the record is concerned, I may not have left the question I had in my mind too clear.

It may well be that in asking you these few questions, I may clarify them.

In 1956, this committee had a witness before it who offered us a statement of principles. There were six of them, which I understood were circulated among and adopted by the various food industry associations after some years of study.

That included the board of directors of the American Bakers Association, the American Institute of Baking, the American Meat Institute, the Dairy Industry Committee, the Grocery Manufacturers of America, the Institute of Shortening and Edible Oils, the Millers National Federation, the American Farm Bureau Federation, and the National Restaurant Association.

I do not care to run over the details of the six, but in his oral testimony the witness said this:

While there are, as I have said, certain differences in language in these statements—

and each of the statements was put in the record—

there is a unanimous affirmation of our belief that there are two basic principles which should be incorporated into the law. They are (1) that the manufacturer or user of any new additive to food shall adequately pretest such additive for its safety in human consumption * * *

I take it that you would be in agreement with that statement.

Dr. SMITH. Yes, sir.

Mr. HESELTON. And that there would be no handicap, so far as the technicians or the scientific personnel were concerned, insofar as the manufacturer's responsibility was concerned. Am I right about that?

Dr. SMITH. Yes, sir.

Mr. HESELTON. The second one is the one as to which I am still somewhat uncertain:

* * * (2) that the results of this pretesting shall be approved by the Food and Drug Administration before the new additive is allowed to be used in or on food, with proper provision for adjudication.

How can that principle be carried into effect if what you suggest as a necessary leeway is given and those who pretest for the manufacturer are not obliged to follow certain standards?

Dr. SMITH. May I ask a question for my information, sir?

Mr. HESELTON. Certainly.

Dr. SMITH. Are they not the same principles which operate in the Miller bill?

Mr. HESELTON. I did not catch that.

Dr. SMITH. Are they not the same principles that are incorporated in the Miller bill, the bill which deals with testing of pesticides?

Mr. HESELTON. Possibly. I am not certain about that.

The thing I am trying to clarify, Doctor, is this question that you have raised, as I understand it, as to the wisdom of writing any legislation which would establish standards which might be a handicap to the scientific personnel who were charged with the responsibility of presenting facts upon which the Food and Drug Administration, or whoever might be given the responsibility, would have to say it is safe.

Maybe I do not understand what you have suggested to us, but it seems to me that you have thrown up a warning against the type of legislation that is involved in the chairman's bill, Mr. O'Hara's bill, or any other. Am I wrong?

Dr. SMITH. No, sir. I have not read the proposed bills, sir. I would say it would be dangerous to describe these scientific procedures in your bill. I believe it would be wise to leave them out of the bill and to leave the question as to whether or not the manufacturer has demonstrated the safety of this mineral to a qualified body of experts, whether they be the Food and Drug Administration or whatnot.

I say that because, depending upon the chemical nature of a proposed additive, it may be necessary to go through this complete 2-year program. But there have been enough instances now where the problem could be solved more easily than that and more simply than that, that I hesitate on two socres:

First, it would be too bad, I think, to force a manufacturer to delay 2 years and to spend the very large sums of money that go into these

tests, when his scientists who are working for him say, "We can prove our point this way."

Second, every time, so far as I am aware, that the scientific people have been able to prove safety by any sound method, there has never been any difficulty in convincing the regulatory authorities; but if these scientific procedures were written into the law, they would take on the aspect of gospel, and one would have to follow them, whether following them was a rational procedure or not, sir.

Mr. HESELTON. I understand you were associated with the Food and Drug Administration for some period of time.

Dr. SMITH. Yes, sir, almost 5 years.

Mr. HESELTON. What was that period?

Dr. SMITH. 1941, sir, in September 1941, until December 1945.

Mr. HESELTON. Did you have anything to do with the socalled Atlas Powder case, involving abread preservative?

Dr. SMITH. I reviewed some of the data at that time, and I was later a member of a National Research Council group which reviewed those data.

Mr. HESELTON. You know that was avery complex case, which took some 18 or 20 months of hearings before the hearing officer; is that right?

Dr. SMITH. Yes, sir.

Mr. HESELTON. And you know that when it got up to the circuit court of appeals, after the Secretary had held it was not safe, it was one of the most complex cases that particular court ever dealt with. Is that right?

Dr. SMITH. I do not know, sir.

Mr. HESELTON. Chief Judge John Biggs, of the third circuit court, appeared before this committee and described that case as one of great complexity, where there was a great area of disagreement among the experts, and his language was:

> Now, the courts cannot act as administrative agencies. Their function must be to review the whole record and decide whether or not there is, on the whole record, a substantial basis for the ruling of the Department—

which seems to me to crystallize the question of whether you have any law or do not have any law.

You cannot relay entirely on the courts to safeguard the rights of either the manufacturers or the public. You have to place that responsibility somewhere.

By the same token, although I am not completely familiar with the record of that case—you must have had scientists on the side of the Atlas Power Co., and you must have had scientists who disagreed with them on the side of the Department which led to the Secretary's finding that the additive in that instance was not safe——

Dr. SMITH. I would say——

Mr. HESELTON. I am left with the dilemma of how do you expect to get any result if you leave it entirely to the scientists to pursue it in what I understand is a perfectly free and proper fashion?

Dr. SMITH. I would say, sir, there existed in the literature at that time adequate advice which, if followed by that company, would have dissipated all their troubles. It may not have gotten the product on the market, but if all the advice which was available to them in the ordinary literature had been followed, the question could have been resolved much earlier.

Mr. HESELTON. Scientists for the Atlas Powder Co. must have testified that the product was safe, is that not true?

Dr. SMITH. Where, sir? Testified where, sir?

Mr. HESELTON. Before the hearing officer.

Dr. SMITH. They must have. I had no part in that, sir. I was not there.

Mr. HESELTON. I beg pardon?

Dr. SMITH. I was not there, sir.

Mr. HESELTON. But were you aware of that fact?

Dr. SMITH. I was aware there was a hearing, yes, sir. Apparently the people retained by Atlas were of the opinion that the material was safe.

As I pointed out earlier, there will always be room for disagreement in this field as long as our knowledge is no better than it is. And freezing the scientific procedures applicable by putting them directly into legislation will not solve this problem, sir.

Mr. HESELTON. If there is always room for disagreement, who do you propose should determine the issue upon which there are disagreements?

Dr. SMITH. I felt that things have worked out pretty well the way they have handled them in the courts, sir. I do not think any injustice was done in that case, if you want my opinion.

Mr. HESELTON. What is that?

Dr. SMITH. I do not think any injustice was done in that case, if you want my opinion.

Mr. HESELTON. No, I am not interested in any individual case. I merely mention that as a case where there was apparently substantial disagreement.

What I would like to get on the record more than anything else is your opinion as to who should resolve these differences of opinion.

Dr. SMITH. Well, one way of doing it is to appoint an ad hoc committee of workers in the field, as has been done in relation to other food additives.

Mr. HESELTON. That is all, Mr. Chairman.

Mr. DIES. May I just ask the gentleman, do I understand that any of the bills before us undertake to prescribe the procedure to be followed? I never heard that question raised, I do not think in 1956 there was any suggestion from any party that you could prescribe any procedure.

Mr. WILLIAMS. I do not think any of the bills we have do that.

Are there any further questions of the members?

(No response.)

Mr. WILLIAMS. Doctor, earlier in your testimony you suggested there should be some good reason for using an additive in food before that additive were used. Were you referring to what has been referred to as the "functional value" of the additive?

Dr. SMITH. I said, sir, if I remember correctly, that in view of the fact one cannot demonstrate with absolute certainty the absolute harmlessness of anything, I thought when dealing with additives one should insist that some benefit accrue to the public, since we could not assure absolute certainty of safety.

I do not think there usually is any substantial doubt about safety. However, when there is that doubt, the public is taking that chance,

however small it is, then there should be some evidence of some benefit accruing to the public. That is purely a personal opinion, sir.

Mr. WILLIAMS. You feel, where there is doubt, that the additive should not be used; it should be established to a reasonable certainty?

Dr. SMITH. It depends upon the degree of benefit. In the case of some chemicals which are fairly highly toxic, it is necessary to use them despite their toxicity.

And take the pesticides, they are very toxic materials. They would not be pesticides if they were not toxic. But we need them to grow crops.

It is the same way with the antioxidants. It may be necessary in some situations that some small risk be taken because of the need for fat in the diet.

In all cases, you must balance usefulness against possible risk, if any.

Mr. WILLIAMS. Doctor, could you give us an example of an additive which is nonfunctional that is used—I will revise that question and ask this:

What would be the purpose of using an additive if it did not serve a functional purpose?

Dr. SMITH. I do not know, sir. I have never thought of using one that did not serve a purpose. I think the question here is whether——

Mr. WILLIAMS. It may be we just do not exactly understand the problem as you do, and that is the reason I am asking these questions.

But these bills say, some of these bills make reference to functional value of an additive.

Mr. DIES. Is not the question there, as I recall it—of course, they do not use it, no manufacturer uses it, unless he thinks there is a functional value, but there is a question of fact whether the particular additive does have a functional value. That is the issue there, as I recall it.

In other words, manufacturer A may say, "I want to use this additive because it has a functional value." But the Department determines that it does not have a functional or useful value. That, I believe, is the problem.

Mr. WILLIAMS. Doctor, could you indicate to the committee an additive which might have functional value to the manufacturer but not to the consumer?

Dr. SMITH. Not offhand, sir.

Mr. WILLIAMS. Mr. O'Brien suggested water in milk. [Laughter.]

Are there any further questions?

(No response.)

Mr. WILLIAMS. If not, Doctor, the House is in session and we will have to recess the hearing.

I take this opportunity, on behalf of the committee, to express our appreciation to you for coming here—I am sure it was at some inconvenience on your part—to give this committee this information which we have obtained this morning.

I think your testimony, as well as the testimony received yesterday, points up the complexity of the problem that is confronting this committee with respect to this legislation, and we appreciate very much the information you have given us.

Dr. SMITH. I hope I have not been merely confusing, Mr. Chairman. Thank you.

Mr. WILLIAMS. The committee will stand adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 12:10 p. m., the subcommittee adjourned, to reconvene at 10 a. m., Wednesday, July 17, 1957.)

FOOD ADDITIVES

WEDNESDAY, JULY 17, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334 New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. The committee will please be in order.

This morning the Subcommittee on Health and Science continues its hearings on several bills dealing with the subject of food additives.

We are pleased to have before the committee this morning Mr. Lawrence A. Coleman, chairman of the chemicals in foods committee of the Manufacturing Chemists' Association, Inc., who will testify from the viewpoint of his organization.

Before I recognize Mr. Coleman for his statement, however, I have a statement to be submitted for the record by Mr. L. S. Hitchner, executive secretary, National Agricultural Chemicals Association, on these several bills.

I submit that for the record.

(The statement referred to is as follows:)

STATEMENT OF L. S. HITCHNER, EXECUTIVE SECRETARY, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

The National Agricultural Chemicals Association is a trade association composed of manufacturers and formulators of agricultural pesticides and related chemicals. Its members produce and distribute more than 90 percent of the agricultural pesticides used in the United States.

We appreciate the opportunity of presenting our views on the food additive bills.

Our purpose is to respectfully call the attention of the members of the committee to the fact that the committee previously approved and the Congress enacted, in 1954, legislation regulating agricultural pesticides. A review of the legislative history of that act, Public Law 518 of the 83d Congress, commonly referred to as the Miller pesticide residue amendment, shows beyond doubt that the Congress intended to regulate pesticide chemicals separately and apart from food additives. We believe that this was a sound decision. Pesticide chemicals should not be classified and regulated as foods, as they would be if subject to the bills now before the Committee.

This legislation already enacted assures the public of a safe food supply insofar as the use of agricultural pesticides is concerned. It eliminates the need of any further regulation of these products. This fact is recognized in all the bills now before the committee, in which efforts have been made to provide a specific exemption for pesticide chemicals.

The term "pesticide chemical" as defined in section 201 (q) of the Federal Food, Drug, and Cosmetic Act means any insecticide, fungicide, weed killer, or rodenticide which is used in the production, storage, or transportation of raw

agricultural commodities. It is in this sense that we use the term in this statement.

In 1954, the House Interstate and Foreign Commerce Committee after very careful study and consideration favorably reported a bill (H. R. 7125) introduced by Congressman A. L. Miller, to regulate pesticide chemicals in or on raw agricultural commodities. That bill became Public Law 518 of the 83d Congress, and section 408 of the Federal Food, Drug, and Cosmetic Act.

The Miller pesticide residue amendment is quite similar in principle to the bills presently before the committee, and, in fact, may be considered to have been the model for many of them. It requires that products be adequately pretested to establish their safety prior to marketing, and that the proposed use be approved by the Food and Drug Administration and the United States Department of Agriculture. The broad objectives of the bills now before the committee are already achieved as regards pesticide chemicals by this existing section 408 of the Federal Food, Drug, and Cosmetic Act.

The Miller amendment was actively supported by our association and the agricultural chemicals industry even though it placed a heavy additional financial burden on the manufacturers of the products involved. It was also supported by the United States Department of Agriculture, the Department of Health, Education, and Welfare, the land-grant colleges, farm organizations, and consumer groups.

That legislation has been in effect for just 3 years. However, its value to all parties concerned with the production of an adequate, safe, and wholesome food supply has been amply demonstrated and attested to. Since it was enacted, over 1,200 tolerances or exemptions have been set for 82 different pesticide chemicals.

In view of the fact that pesticide chemicals are now adequately regulated, there appears to be no reason to involve them in the proposed legislation now before the committee.

As previously mentioned, all the bills now before the committee contain provisions to exempt pesticide chemicals which are under the Miller pesticide residue amendment. In a few instances, the wording of the exemption is such that there could possibly be in the future some differences of opinion as to its interpretation. To remedy this situation, we will submit shortly a supplemental statement containing suggested amendments to clarify the intent and scope of the exemptions for pesticide chemicals.

We are not acquainted with the technical and legal aspects of the use of chemicals in or on food other than those applied in the production, storage, and transportation of raw agricultural commodities. For this reason, we do not feel qualified to pass comment on the specific previsions of the various bills which would regulate the use of food additives. Accordingly, we have restricted our remarks to the status of pesticide chemicals in relation to the pending legislation.

Your consideration of the foregoing is greatly appreciated.

Mr. WILLIAMS. Mr. Coleman, the committee is pleased to have you before us, and we will be glad to have your statement.

STATEMENT OF LAWRENCE A. COLEMAN, ON BEHALF OF MANUFACTURING CHEMISTS' ASSOCIATION, INC.

Mr. COLEMAN. Thank you, Mr. Chairman.

My name is Lawrence A. Coleman. I appear before this committee as the representative of the Manufacturing Chemists' Association, which is a trade association composed of approximately 160 corporate members which are engaged in the manufacture of products generally referred to as chemicals.

Initially, I should like to say that, on behalf of the association, we wish to thank your committee for the opportunity you are giving us to appear here before you in support of legislation to amend the Federal Food, Drug, and Cosmetic Act.

The Manufacturing Chemists' Association believes that there is a need for legislation in the food-additives field. This is a belief which

we have expressed before congressional committees and other public groups over a period of the past several years.

We further believe that there are both good features and unworkable or impracticable features in many of the bills that have been introduced to date on this subject. Weighing the good features of the various bills against the unworkable or impracticable features, it is the opinion of our association that the bills which have the greatest number of good features, and the least number of features calling for amendment, are the bill introduced by Chairman Harris, H. R. 8390, the companion bill introduced by Representative Wolverton, H. R. 8629, and the bill introduced by Representative O'Hara, H. R. 366.

However, before discussing these bills in detail, I should like to review briefly the historical background. As I am sure all of you are aware, the first Federal food legislation in this country was enacted in 1906, its enactment having been brought about by the serious concern expressed in many quarters that the public health was being adversely affected by the careless inclusion of filth in meats, flour, and a wide variety of packaged foods; and the deliberate addition of substances, such as formaldehyde to milk, to mask the effect of its age.

Thus, the first Food and Drug Act was designed to exclude from foods, materials which had no place in the diet and which could reasonably be expected to be harmful to the consumer.

The act at that time did not touch upon the problem of the deliberate addition to food of additives designed to improve the nutritional value of food, its quality, its esthetic appeal, or to scientifically reduce the perishability of food products.

The 1938 amendments to the Food and Drug Act, among other things, modified the law so as to recognize that, in some instances, in the preparation of food it might be necessary or inevitable to add thereto substances which the act classified broadly as "poisonous" or "deleterious" materials.

The 1938 act granted the Secretary—then the Secretary of Agriculture; now the Secretary of Health, Education, and Welfare—the power to fix tolerable limits for such unavoidable ingredients.

Even with this salutary amendment, and even with this statutory recognition that tolerances could and should be fixed for certain materials which may be harmful in gross quantities, with the advances in techniques of food processing, the act today leaves a great deal to be desired.

There is no provision in the present law, as I have said, even with the 1938 amendments, which covers the situation where a food processor, for a beneficial purpose, adds to a processed food an ingredient not naturally occurring therein.

The absence of provisions in the law covering this matter has been demonstrated over the years to be both inadequate and undesirable from the point of view of not only the Food and Drug Administration, but also from the point of view of those in industry and agriculture whose efforts produce the nation's food supply.

The absence of provisions in the existing law covering the deliberate addition of food additives has left the Food and Drug Administration in the position where they are not readily able to determine precisely what additives are in the food supply and hence are unable

to exercise their directive of insuring full protection of the American health.

The absence of such provisions in the law similarly has left industry in a position where they constantly fear that some unscrupulous person can use food additives which are harmful to the public health, in which the public as well as the careful and reputable processor of foods could suffer from the acts of the unscrupulous few.

Fortunately, the fears of industry as above expressed are not based on actual events. It is to the great credit of both the Food and Drug Administration and the food and chemical industries that, to our knowledge, there have been no incidents of serious food poisoning occasioned by the use of deliberate food additives.

It should also be borne in mind that at the time of the passage of the 1938 amendments, chemistry, and particularly food chemistry, had not yet achieved the great advances that have been made in the past 19 years.

Countless millions of dollars have been spent by the food industry and the chemical industry in finding methods to improve, increase, and better the food supply. Much of this has been done since the passage of the 1938 act.

Modern techniques, modern knowledge, demand a modern law. A modern law, we respectfully submit, is one in which it is made eminently clear that deliberate additives beneficial to the consuming public should be permitted to be used in safe quantities, notwithstanding the fact that it may be demonstrable that some of these beneficial additives could, in gross quantities—that is, quantities bearing no relationship to the amounts actually ingested—cause adverse physiological effects on test animals.

In substance, what this means is that we must divorce from our thinking and from the administration of the food laws the idea that "poisonous" or "deleterious" are absolute concepts; that a food additive can be denominated a "poison" without reference to the quantity ingested by a human being.

We must, in our thinking, adopt the view that the true test to insure protection of the public health is safety under the conditions of use and that the principal condition of use is the quantity used and that, therefore, the statutory word "poison" is a relative concept.

Before determination of whether a substance can be so classified, one must ask two questions—not only the classical "What is it?"—but secondly, and of equal importance, "How much?"

It is exceedingly gratifying to the chemical industry that all of the bills pending before your committee have adopted this modern scientific approach to the problem of determination of whether or not a particular ingredient may be used in food.

As the spokesman for this association testified last year:

> A year ago (1955) we reemphasized our adherence to five basic principles which we believed would command widespread support as the basis for strengthening the Food, Drug, and Cosmetic Act. These may be stated as follows:
>
> 1. That every new additive proposed for use in food must be tested by the manufacturer before being publicly used.
>
> 2. That the manufacturer's test data and other relevant information must be submitted to the Food and Drug Administration before the additive can be used.
>
> 3. That the manufacturer must bear full responsibility for his own compliance with the law, but that no man should be his own referee as to safety and the adequacy of testing for safety.

4. That the matter of safety should be decided in keeping with the basic concepts of the modern science of toxicology, and not on a categorical rule-of-thumb basis, and that it should depend on a realistic appraisal of relative factors which apply in use.

5. That the Food and Drug Administration should be provided with an adequate method of preventing the sale in advance of use of additives which have not been adequately tested for safety or which have been shown by testing to be unsafe.

This year we repeat and reiterate this statement as a sound basis for congressional action.

Let us now, if we may, come to a consideration of the specific bills which are before this committee. The differences in major part are procedural rather than substantive. Administrative law, as it has developed in this country under our system of jurisprudence and free enterprise, has, thankfully, in most instances developed on the basic philosophy that the administrative tribunal charged with the responsibility of regulating human conduct in a particular field has been granted the power to police that human conduct.

By "police" here is meant that the administrative tribunal has been empowered to set the rules of the game and to arrest or fine or enjoin the miscreant when his conduct violates the rules.

This is the classical method of enforcement of all criminal and quasi-criminal activities—the clear expression of the rule, and the punishment if the rule be violated.

The Food and Drug Administration under the 1906 and 1938 acts has just that type of authority. The philosophy behind those laws, after stating what should not be included in food, stated further that if the banned materials were contained therein, the food could be seized, or the manufacture or shipment enjoined and a penalty imposed for violation of the rule.

The Manufacturing Chemists' Association is gratified to see that in several of the bills pending before your committee, particularly H. R. 8390, introduced by Chairman Harris, and H. R. 8629, introduced by Representative Wolverton, and H. R. 366, introduced by Representative O'Hara, the police power method of enforcement has been retained.

The basic pattern of these bills may be stated, I believe, in three sentences:

First, a processor or producer who proposes to sell or use in food a new food additive so notifies the Food and Drug Administration.

Second, accompanying that notice, the proposer of the food additive presents to FDA the results of pharmacological, toxicological and other scientific tests which have been run on the proposed additive to insure its safety for consumption in the proposed quantity.

Thirdly, these bills would add to the Food and Drug Administration's enforcement tools by, in the case of H. R. 8390 and H. R. 8629, giving the Administration the specific authority, in advance of the use of the additive, to enjoin the sale or transportation of a food additive or a food containing that additive if the Administration has not been persuaded that the testing data established safety under the conditions of intended use.

Moreover, this injunction would be implemented by a temporary restraining order which would forthwith issue upon application without the necessity for demonstrating the accuracy of the Administration's views.

Mr. O'Hara's bill, H. R. 366, would modify this latter by providing for a declaratory judgment proceeding rather than an injunction.

These three bills thus continue the historical method of enforcement by exercise of the police power, but they also give the Food and Drug Administration several things it has never had before: to wit, clear statutory direction that any producer or user of a new food additive must advise the Food and Drug Administration in advance that he proposes such sale or use and he must pretest the proposed additive to establish its safety under conditions of its intended use. Similarly, as I have just stated, it adds also another enforcement tool.

With a minor modification in the language of the grandfather clause, which would permit a more orderly changeover from the old law to the new and which would reduce the burden of costly pharmacological studies on the small processor who has for years been processing a food additive that has caused no harm, the Manufacturing Chemists' Association strongly urges upon your committee the passage of Chairman Harris' bill and its counterpart, Representative Wolverton's bill.

A marked copy of H. R. 8390 with the amendment will be given to the committee's staff. We also support Representative O'Hara's bill, H. R. 366.

In addition to the bills to which I have referred, your committee has before you the bill proposed by the Food and Drug Administration itself, H. R. 6747. Again, I wish to repeat that the Manufacturing Chemists' Association looks with great favor on so much of H. R. 6747 as makes clear that the test of whether an additive may be used in a food depends on the determination of its safety under the conditions of its use and in the quantity proposed for use, rather than basing the acceptance or rejection of any food additive upon the nebulous—nebulous, that is, in the light of modern-day science—concept that some substances are and others are not "poisonous," without respect to the quantity ingested.

We are similarly gratified to note that the Food and Drug Administration has itself proposed a bill, for the first time since these discussions began, thus crystallizing the alternatives that are before your committee and giving full expression to whatever opposing views there may be.

Parenthetically, I should like to state here that I am sure your committee realizes that the ultimate objective sought by all the groups that have testified and will testify here before you is the same. All these people seek the same end: All these people desire that the American health be protected. All desire that the food supply be bettered. All desire that the method of betterment, the method for protection, be orderly.

The ends are the same. The means to achieve these ends may vary.

The Manufacturing Chemists' Association, though they find much in the Administration's bill, H. R. 6747, which they believe good and appropriate to achieve the ends which we all have in view, do not believe that the Food and Drug Administration should be granted the power to license the use of an additive.

As stated before, we subscribed to the continuation of the classical methods of enforcement of this act. Licensing contradicts, in our opinion, many of the fundamental concepts of our jurisprudence.

H. R. 6747 is essentially a licensing bill. The proponent must, under its terms, beg leave of the Administration before an additive can be used in food, notwithstanding the fact that it is his conclusion, based on costly pharmacological and toxicological studies—a conclusion which he stands ready to support before any court—that the potentiality for harm to the consumer from its use is nonexistent.

The evil of this type of bill, as we see it, is not found in the licensing provision alone, but in its concomitant sections providing for a review of the Administration's denial of the leave which has been begged.

As you all here are well aware, the Administrative Procedure Act makes clear that if there be any substantial evidence on the record as a whole which supports the Administration's denial of a license, the court of appeals must confirm the Administration in such denial, even though the weight of the evidence, the preponderance of the evidence, would indicate that the license should have been issued.

Licensing alone is, in our opinion, unwise. Licensing accompanied by the limited review afforded by the Administrative Procedure Act is, in our opinion, seriously detrimental to future progress of food technology; is detrimental also to continued progress in the science of toxicological testing, and of all the other scientific activities engaged in by the food and chemical industries which over these many years have made the American food supply the most nutritious, the most wholesome and most abundant in the world.

However, should your committee see fit to report out H. R. 6747, the Administration bill, we feel as a minimum there are a number of specific amendments which we should propose. If I may beg your indulgence to hear me further, I should like as briefly as possible to state what we believe those amendments should be and the reaosns why they should be made.

In addition to its basic defect of granting licensing power to the Food and Drug Administration, H. R. 6747 embraces 3 or 4 other provisions which we feel must be amended for the reasons set forth below.

The Administration's bill would require that before an additive coming under the bill's definition could be used, the proponent of its use would be required to satisfy the Food and Drug Administration that the particular additive in the proposed use has a "functional value." These words are not elsewhere defined.

We join with what we are informed is the overwhelming consensus of food manufacturers that any legislation in this field should concern itself only with the safety of food additives in their intended use, and should not deal with any such concept as the functional value of any additive.

We believe that no food additive will be purchased by a food processor unless the purchaser believes it has some value, functional or otherwise. It is for the purchaser and not the Government to say whether any product has value. Value is to be determined in the market place, and not by administrative decision.

The definition of an additive contained in section 2 of H. R. 6747 is, in our opinion, far too broad. I quote:

> * * * any substance * * * which * * * may result, directly or indirectly, in becoming a component or otherwise affecting the characteristics of any food * * *

would embrace granting to the Food and Drug Administration plenary control over a myriad of substances as to which the Food and

Drug Administration has no real interest and as to which, we are sure, Congress has no intention of subjecting to the Administration's control.

Using paint in a food processor's plant could result in its becoming a component of food. Yet paint is not a proper material for enforced toxicological and pharmacological testing.

This is but one example of what we mean. Many others will immediately come to mind. A better, more workable, and more realistic definition would be to say that the legislation is designed to cover additives which could reasonably be expected to become components of food.

We believe further that the bill should contain a clear definition of "safe," and to that end we would propose the use in this bill of the definition of 'safe" promulgated by the National Research Council.

The bill as presently drawn omits any definition of "safe" or "safety," but does state that no additive may be used unless it "will be without hazard to the health of man."

Few, if any, substances, natural or synthetic, can meet this test. Rhubarb contains relatively large quantities of oxalic acid, a material subject to regulation under the Federal Caustic Poisons Act.

Common table salt is toxic if injected in large quantities. Some orientals have been known to commit suicide by drinking massive quantities of water.

Another fundamental change we feel would have to be made, were this committee to report favorably on the Administration bill, is in the provisions for review of the orders of the Food and Drug Administration. As was mentioned above, a licensing law with only an Administrative Procedure Act review could readily bring about a denial of justice.

The Present Food, Drug, and Cosmetic Act, in its new Drug Section, now provides for a district court rather than a court of appeals review. We would propose that this type of review be adopted, and that in such a review the appellant be, if the court so orders, permitted to adduce additional evidence.

We would further propose that the order of the Secretary is to be set aside if, in the opinion of the district court, it is contrary to the preponderance of the evidence. Such a procedure would afford protection against arbitrary action in a field where emotional pressures may be brought to bear against the Administration.

Another important omission from this bill is provision for an orderly method of transition from the legal procedures now in effect for policing the use of food additives to the new procedures which would be in force if H. R. 6747 were enacted.

To accomplish an orderly transition to the proposed new law, we urge the adoption of an adequate grandfather clause which would provide that all food additives in use at the time the new law becomes effective would continue to be policed under the old law until and unless a regulation respecting the use of such additives is issued pursuant to provisions of the new law.

The amendments discussed above, as well as others we urge, are spelled out in a marked copy of H. R. 6747 which we have filed with the clerk of your committee.

On behalf of the Manufacturing Chemists' Association and myself, I wish to thank you for the time you have given us this morning.

Mr. WILLIAMS. Thank you, Mr. Coleman.

Some of the members of the committee may have questions which they would like to propound to you, and I will recognize Mr. Dies first.

Mr. DIES. If I understand your testimony, Mr. Coleman, you endorse the Harris bill with the suggestions for modification and amendment contained in your statement. Is that right?

Mr. COLEMAN. That is so, Mr. Dies. We endorse H. R. 8390, introduced by Chairman Harris.

Mr. DIES. Under the present law, of course, there is no pretesting required. However, if you put on the market an additive which is poisonous, does it not use the words "poisonous or deleterious"?

Mr. COLEMAN. Yes, the present law does use both the word "poisonous" and the word "deleterious."

Mr. DIES. But in using the term, it does not define the question of quantity, is that right?

Mr. COLEMAN. No. Except that in one instance, in section 406 (a) of the present act, where it indicates that if a material must of necessity or inevitableness be included in a food, then it says even though it be a poisonous or deleterious substance, it may be included, but under quantitative limits fixed by the Secretary under a particular petition in each instance.

Mr. DIES. But that is not very clear.

Mr. COLEMAN. We feel it is not, sir.

Mr. DIES. Under the present law, if, as I say, you should market some additive, then the Food and Drug Administration can stop you by injunction.

Mr. COLEMAN. That is so, sir.

Mr. DIES. They can go into the district court and apply for an injunction, and allege that the additive is poisonous or deleterious for human consumption, and then you have a trial.

Mr. COLEMAN. Yes, sir.

Mr. DIES. The burden is on the Government to prove their case, is that not true?

Mr. COLEMAN. That is so, sir.

Mr. DIES. Are you entitled to a jury in those trials?

Mr. COLEMAN. Insofar as they are criminal proceedings, I believe under the laws of most States you would clearly be entitled to a jury trial. Where it was an injunction, normally, as I am sure——

Mr. DIES. Well, a temporary injunction would not have a trial by jury on your injunction.

Mr. COLEMAN. Normally, an injunction proceeding is not a jury proceeding.

Mr. DIES. But, of course, when you get into the question of fines, they have a right, also, to impose a fine.

Mr. COLEMAN. That would be a criminal proceeding, and in that instance a jury could be had.

Mr. DIES. You would be entitled to a jury trial, and from there you would have the same appellate remedy you would have in any other case.

Mr. COLEMAN. That is so, sir.

Mr. DIES. You believe that that law ought to be—and also, under the present law—you have a high degree of responsibility in the civil courts, do you not?

Mr. COLEMAN. Oh, yes, sir.

Mr. DIES. I mean, if any product were sold that contained an additive which was poisonous or deleterious, not only would the retailer be responsible, but you, as the manufacturer of the additive, would be responsible without any defense; is that right?

Mr. COLEMAN. Well, there may be some defenses left to a manufacturer.

Mr. DIES. I mean if it was poisonous, you would not have any defense.

Mr. COLEMAN. Again, sir, on that issue, we must define what we mean by "poisonous." The chemical industry manufactures many products which could be classified under the broad definition contained in the law as "poisonous," substances which are not designed for food at all.

If somebody takes one of those products and puts it in a food and thereby injuries a member of the consuming public, I am certain that no liability would lie against the manufacturer.

Mr. DIES. I was not assuming that sort of a premise. I am assuming the premise that you put on the market a substance or an additive that is poisonous and deleterious. You are responsible without any defense, if they can prove that it is, as a matter of fact, poisonous.

Mr. COLEMAN. It is exceedingly difficult, Congressman Dies, for a lawyer to say that under any circumstances he would have no defense.

Mr. DIES. I know you have some. I have seen some of those cases tried, and tried them myself. But what I am trying to say is, you have a high degree of responsibility under the existing law.

Mr. COLEMAN. There is, sir; there is constantly imposed upon us a high degree of responsibility toward the consuming public.

Mr. DIES. Do you think we ought to change the present law so as to provide for pretesting?

Mr. COLEMAN. I do, sir.

Mr. DIES. In order to protect the health and welfare of our people. Do you think all additives used should be pretested?

Mr. COLEMAN. I feel that there are many additives which, over the years, have been used in such a way and in such quantities and whose use has been so widespread that any group of persons appropriately trained in the field would say there is no potentiality for harm in their continued use, and therefore they should be exempted.

Mr. DIES. Right at that point, how can we accomplish that exemption with any degree of certainty or fairness? The approach which was made here in 1956 in this bill was simply to have a rather vague definition, which I of course know was used in other acts, but still it seems to me it could be the source of a lot of trouble, simply if it is recognized generally by experts in the field as being safe, then you have a right to use it. That is the standard.

That imposes a burden upon each manufacturer of an additive to determine for himself whether or not that additive has been generally recognized by experts in the field.

What troubles me is that most experts I have seen, in every field, disagree violently on every question. I have never seen a question, either in law, politics, medicine, or anything else, that you could assemble any group of men and get them to agree on it.

So that what I fear is that we ought to have some more certain way of eliminating from the operation of any act all those additives

which have been used for years and have been generally accepted as safe, so that those additives would not be under this law.

What do you think about that?

Mr. COLEMAN. I think two things, sir: In the amendment which we propose to H. R. 8390, I think that purpose would be accomplished in the grandfather clause.

I secondly say that even were H. R. 6747 or some such similar bill enacted, it would be our hope that the Food and Drug Administration in its regulations would provide a so-called white list, and in the preparation of that white list, which would be a list of foods or additives which would be permitted to be used in food without subjecting them to pharmacological or toxicological——

Mr. DIES. There is no requirement for that. You just hope they will do it.

Mr. COLEMAN. I say that under their bill, H. R. 6747, as we would like to see it amended, we would hope they would do it.

Mr. DIES. Under the grandfather clause, there is some merit to it if it is not a fixed proposition. But with the great advances in science, it is quite possible that some of the additives which have been accepted may, through new probing, be determined to be unsafe in the future. So you would want to leave the door open for that sort of eventuality, would you not?

Mr. COLEMAN. Under our proposed amendment to H. R. 8390, the old additives would be continued under the present act until such time as the regulation would issue changing that; and that regulation, we would anticipate, would issue when and in the event the Food and Drug Administration determined, from its additional toxicological studies, that there was some question of safety.

Mr. DIES. You leave the door open, in other words, for it; it is not a static situation.

Mr. COLEMAN. The door is left open. That is so.

Mr. DIES. Is it possible something can be written into the bill providing an adequate period for the determination, once and for all, or at least not on a fixed, unalterable basis, but a determination of what additives will be exempt from the act so as to remove the great uncertainty?

In other words, suppose that the act—I do not know whether this is right; I am just simply trying to get some information, because I went through the hearings in 1956, and I know there are some very serious questions involved in the proposed bills.

I am wondering if one solution of it would be to defer the operation of the act until such time, by administrative action, as that thing could be cleared between the manufacturers and the Administration as to all additives that would not require any pretesting.

Mr. COLEMAN. Well, sir, in the Administration's bill, H. R. 6747, there is, as you will recall——

Mr. DIES. A 180-day period.

Mr. COLEMAN. Well, there is also a 2-year period. It reads, on page 16 of that bill, beginning on line 5:

"Where"—and I might say here, gentlemen, if I may digress for a moment, we would very much hope that any bill to come out of this committee would use the term "food additive" rather than the term "chemical additive." The Administration bill continues the use of

the term "chemical additive," which we find is exceedingly difficult to understand in terms of precise definition; whereas we feel the term "food additive" is clearer.

But to go back, on page 16 of H. R. 6747, at line 5, we find these words:

> Where a food additive was in use for one or more purposes prior to the date of the enactment of this Act, the amendments to sections 402 (a) * * * shall not, as applied to such preexisting use or uses of such additive, become effective until—

and then it provides——

Mr. DIES. How long a period have they got?

Mr. COLEMAN. It says that the amendment to the law does not become effective until—

> (1) the final establishment of a regulation or exemption relating to such use or uses pursuant to section 409 * * * or
>
> (2) if earlier, the expiration of either (A) the one-year period beginning on the date following the effective date of this Act, or (B) such additional period (not extending beyond two years after the effective date of this Act) as the Secretary of Health, Education, and Welfare may prescribe * * *

In other words, they say there is an automatic one-year period; the Secretary is given discretionary authority to extend it to two.

We feel very strongly, and in the copy of the bill that we have handed to your clerk we have so shown, if this bill be adopted in this form, we feel that that 2-year period should be extended to 5, which gives, we feel, an adequate period of transition so that these problems of old additives, whether they may be continued to be used in the absence of any evidence of harm, can be worked out satisfactorily between the food industry, the chemical industry, and the FDA.

We feel 2 years is much too short a period.

Mr. DIES. You agree, of course, as you say, to pretesting, but you do not want any license.

Mr. COLEMAN. That is so, sir.

Mr. DIES. You do not want to give the Government the right to license.

Under the Harris bill, what would be the practical application. Say you are a food manufacturer, and the bill goes into effect, what would you be required to do?

Mr. COLEMAN. I would be required to advise the Secretary that a certain number of days after the notice I have given him, I propose to ship in interstate commerce a food additive or a food containing such additive; and I would be required to give him, at the time I gave him that notice, all of my pretesting data.

If he took no action, then at the expiration of the notice period I would be permitted to ship the material in interstate commerce.

Mr. DIES. And if he took action, what action would he take?

Mr. COLEMAN. Under H. R. 8390, he would have the power to enjoin, based on the information he would have available, including (*a*) what we were proposing to use, and (*b*) our pretesting data. He then would have the power to seek an injunction to restrain the shipment of the material in interstate commerce, and in the first step of that proceeding he could procure a restraining order merely on the application therefor, without supporting documentary evidence.

Mr. DIES. That is under which bill?

Mr. COLEMAN. That is under H. R. 8390.

Mr. DIES. Under the Harris bill.

Mr. COLEMAN. Yes, sir.

Mr. DIES. Then you would go through the courts with that?

Mr. COLEMAN. Then we would go through the courts, starting with the district court, in a normal injunction procedure.

Mr. DIES. Which bill contains the present administrative procedure in it for substantial evidence which is used generally in the Administrative Procedure Act?

Mr. COLEMAN. The administration bill, sir, H. R. 6747.

Mr. DIES. That is not in the Harris bill or the O'Hara bill?

Mr. COLEMAN. Well, since the Harris bill, H. R. 8390, and the O'Hara bill, H. R. 366, provide a different method of review, that is, district court action, either declaratory judgment action or injunction, the Administrative Procedure Act would not be an appropriate method, because you would go as a de novo matter into the district court and, therefore, it is not an appeal from an administrative review, but it is an action——

Mr. DIES. The Harris bill does contain that?

Mr. COLEMAN. The Administration bill, as introduced by Chairman Harris, H. R. 6747, does contain a provision that the review of the Secretary's order shall be under the provisions of the Administrative Procedure Act, yes, sir.

Mr. WILLIAMS. That is the Administration bill.

Mr. COLEMAN. H. R. 6747.

You understand, Mr. Dies——

Mr. DIES. I did not understand, that is what confuses me, that Mr. Harris had introduced two bills.

Mr. COLEMAN. Yes. It is both H. R. 8390 and H. R. 6747.

Mr. DIES. What your viewpoint is, you do not want the administrative procedure now used in the bill of the Department?

Mr. COLEMAN. We want the method of enforcement to be the classical method of injunction or declaratory judgment or seizure, rather than the order of the Secretary under the licensing provision merely being reviewable under the Administrative Procedure Act.

Mr. DIES. Do you not think the injunction method would be preferable to the declaratory judgment? If something was being put on the market that was harmful, how could you stop it through a declaratory judgment as quickly as you could through an injunction?

Mr. COLEMAN. Well, our position is that we recognize, Mr. Dies, that there are some weaknesses which are said to be present in the declaratory judgment method. You will recall that at the last hearings, Mr. Larrick, of the Food and Drug Administration, testified that in his opinion it would impose a jury trial, which he did not think was a wise thing.

Many other procedural objections have been expressed. Our choice in the matter would be the injunction procedure, for the very reason that you mentioned.

Mr. DIES. If you adopted a procedure which would provide for a jury trial you would be submitting to laymen highly technical questions, would you not?

Mr. COLEMAN. That is so, sir.

Mr. DIES. And it is rather difficult to believe that those laymen would be qualified to pass on such questions.

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But under the injunction route, of course, if you violated the injunction, then you would be entitled to a jury trial.

Mr. COLEMAN. Yes, sir.

Mr. DIES. As a matter of fact, everybody would be entitled to that except people under the Civil Rights bill. [Laughter.]

I will not ask any more questions, because I am taking up too much time, Mr. Chairman.

Mr. WILLIAMS. Mr. Heselton?

Mr. HESELTON. I would like to ask for a little more information, Mr. Coleman, on your discussion with Mr. Dies about the grandfather clause.

Mr. COLEMAN. Yes, Mr. Heselton.

Mr. HESELTON. As I understand it, your statement with reference to that places you squarely in opposition to the Food and Drug Administration. It is nothing new. It is something which has been before us for some time.

I think the position of the Food and Drug Administration could be stated fairly as being in opposition to what they call a blanket grandfather clause because it would place approval, an approval seal or seal of approval, by Congress on continued use of chemicals which they call of questionable safety.

I am not sure from either what you said to Mr. Dies or in connection with your comments on H. R. 8390, which is the second bill filed by the chairman, Mr. Harris, in which you refer to a minor modification of the language or submitted a more orderly change of it, or from what you said in your statement at the bottom of page 13, as to what you would recommend as an adequate grandfather clause in connection with H. R. 6747, which I understand is what has been called the Administration bill filed by the chairman.

Mr. COLEMAN. Yes, sir.

Mr. HESELTON. Unfortunately, I do not have the marked copy that you say you furnished to the clerk——

Mr. COLEMAN. May I, sir, read to you——

Mr. HESELTON (continuing). Or a marked copy of either bill. You did quote something rather rapidly. Which bill were you referring to?

Mr. COLEMAN. Let me, sir, read to you, if I may, the amendment we would propose to be made in that bill, were this committee to favorably report H. R. 6747.

On page 2 of the bill, we would propose the addition, at the end of present line 23, of the following language—you will note that this subsection (2) starts off, "Such term," and the word "term" there means, "food additive," in line 15. It says:

> Such term does not include (A) a pesticide chemical * * * or (B) any substance used in accordance with a sanction * * *

and we would add thereto:

> or (C) any substance which prior to the effective date of this Act was used in the United States in a particular food or class of foods under the conditions of its intended use, until there is in effect with respect to the use of such additive a regulation issued under section 409.

Mr. HESELTON. Before you comment on that, what is the language you propose in H. R. 8390? Is that identical, or different?

Mr. COLEMAN. We would propose, as to H. R. 8390, the addition at line 19 of page 2 of the following language:

*** * * or (C) any substance which prior to the effective date of this Act was used in the United States in a particular food or class of foods for the intended purpose * * ***

Mr. HESELTON. Are they identical?

Mr. COLEMAN. No, they are not, sir.

Mr. HESELTON. Are the two bills identical?

Mr. COLEMAN. The language of the two amendments is not identical. In H. R. 8390 we do not add the phrase "until an order under section 409 is effective." In other words, the suggested amendment to H. R. 8390 is the blanket exemption to which you earlier referred. Whereas the proposal we make to conform, as best we could, to the Administration's views in H. R. 6747, would permit the Administration to lift the blanket, in other words, in the event they determined subsequently that there was some new evidence of potentiality for harm of any particular additive.

Mr. HESELTON. In other words, in the so-called Administration bill——

Mr. COLEMAN. Yes, sir.

Mr. HESELTON (continuing). You add a clause which would place a burden upon the Administration, in this instance the Food and Drug Administration, to establish by regulation the absence of safety in regard to any additive that had been used heretofore, or before the passage of the bill. Is that right.

Mr. COLEMAN. I think substantially; yes.

Mr. HESELTON. Why do you place the burden on the Food and Drug Administration when, as I understand it, you state that these existing additives have been the subject of very considerable scientific study on the part of the manufacturers, and that they are in position to come in court—perhaps I do not quote you correctly, and correct me if I misunderstood something you said—on judicial review and establish their case?

Why should not the burden be on the manufacturer?

Mr. COLEMAN. Well, sir, I think—where I mentioned coming into court, I was referring to a new food additive, where a man proposes an additive, a new food additive, for use, where he has made his toxicological and pharmacological studies and has advised the Administrator of the results of those studies and is convinced it is safe under the conditions of intended use.

Mr. HESELTON. I see.

Mr. COLEMAN. I do not think it is correct to say we are casting the burden on the Food and Drug Administration. All our amendment to H. R. 6747 would propose would be that, since we know there are additives which have been used, since they have been used for years, since there is apparently, so far as we know, no evidence of serious food poisoning occasioned by the use of those additives, that they may be continued unless the Administration, because of new evidence or additional evidence or new knowledge it has which indicates that perhaps there is question as to the safety of those, then goes through the procedures provided for in H. R. 6747 for a license, if that be the bill, and the burdens of proof for the old additive then become the same as are provided in the bill for the new additive.

Mr. HESELTON. My trouble in understanding that position is that I would suppose that any manufacturer who had been using—and I will use the term you want to use—food additives over a period of time, would have established ample evidence of safety; whereas in dealing with a new additive, the difficulty might be very great because of the lack of opportunity of testing so as to present evidence in a short period of time that it was safe.

If you say that the manufacturer is in a position to come in, as you did say, I think, in the first of the testimony I heard, and establish this affirmatively, I would think it would be easier for him to do so in connection with something he had used over a period of time and human beings had consumed over a period of time without injurious effects, than it would be in the case of a new additive that he proposed to use.

Mr. COLEMAN. That may or may not be so, Mr. Heselton.

You see, take as an example sodium benzoate. It has been used for years in food, and I do not know the facts on each one of these chemicals, I do not know anything about this one, but it would surprise me if there was anywhere near as complete a pharmacological or toxicological study on sodium benzoate as would be required, under any of these bills, to be made and furnished to the Administration before the use of a new additive.

The evidence of the safety of the old additives is, to some extent—not wholly, to be sure, but to some extent—the strongest piece of evidence is the long use of the additive without harm.

Mr. HESELTON. That is it. It is the long use without harm which is the strongest piece of evidence they could present. Why, then, are you so concerned about the need of this grandfather clause in both instances, when you have what seems to me to be, as you say, the strongest evidence they could present?

Mr. COLEMAN. Because, sir, we are under the impression, and I think properly so, that should H. R. 6747 be enacted, it would cast suspicion on every additive that has heretofore been used. Because there is in nobody's hands the complete pharmacological and toxicological studies that this new bill would require.

Mr. HESELTON. Are we not confronted with a proposition that grows out of this relatively recent use of the so-called food additives, or what other people call chemical additives, and have there not been presented to the Congress, through the Delaney committee, instances in which continued use of the so-called old additives is injurious or has been injurious and, therefore, do we not—it is getting to be a complicated question, and you can separate it any way you want—but do we not have a very real problem, when you urge a grandfather clause upon us, of weighing the relative difficulty that may be involved so far as the manufacturer is concerned?

I agree there might be an element of suspicion cast on the entire list, but I rather think one that could be cleared up rather quickly in terms of the safe use of it or putting out what I think you called at one time a "white list"—did you refer to a white list?

Mr. COLEMAN. Yes, sir; I did, sir.

Mr. HESELTON (continuing). Which would blanket everything, whether it was injurious or not.

Mr. COLEMAN. No, by a white list, I did not necessarily mean that I meant the Food and Drug Administration would publish a white

list of those additives which, in their opinion, based on whatever evidence they had or desired, they felt were safe for continued use. It would not blanket the harmful ones.

Mr. HESELTON. Let me ask you another practical question: Is the expense involved a factor in your concern about the procedure that is suggested in the bill first filed by the chairman of the full committee, H. R. 6747?

Mr. COLEMAN. Whereas I hesitate to say, in a matter of as great importance as the measuring of the best methods of protecting the public health, that money is a factor, it is for the small companies.

Mr. HESELTON. To the small companies?

Mr. COLEMAN. For the small companies.

The large ones can probably readily afford the high cost; but for the little fellow, it is a very difficult thing to find out now, under the Administration bill—when he has been making product X and selling it for 30 years successfully, with no civil liability imposed upon him for injuring anybody, no evidence that his product has ever, when included in food, injured anybody—to find now by the passage of this bill that he must expend thousands, perhaps hundreds of thousands, of dollars to test pharmacologically and toxicologically the substance, which would have no more effect than to assure him what he has known all along, that the material was, in the quantities in which it is used, not capable of injury to man.

Mr. HESELTON. Just one further question.

I went over last night the testimony of Mr. Gillett——

Mr. COLEMAN. Yes, sir.

Mr. HESELTON (continuing). Which he gave us in 1956, and there was one portion I marked, because I do not think it is documented. It is at page 117 of the hearings in 1956. He said:

> It is only in the relatively few instances that the manufacturer refuses to accept the veto of the FDA scientists on his product because of scientific advice to him to the contrary and determines to proceed that legally trained persons enter the picture.

That was a letter furnished after the hearings had closed. Did he mean by that, scientific advice furnished to him by persons the manufacturer engaged, or so-called objective scientific advice?

My friend raised a question, and I think very properly, I know he meant no reflection, and I mean no reflection, upon the sort of expert advice that anyone can obtain. I assume that you do get into a clash between advice received from someone retained by X company which is intended to establish the safety of the additive, as against the advice that the Administrator has to accept or does accept from other scientists, that the additive is not safe.

Mr. COLEMAN. Well, in this field, Mr. Heselton, we are not quite in the same field that you are in such as a normal legal proceeding where the experts disagree. The disagreement arises not so much as to factual data, whether an X-ray shows a broken leg or does not show a broken leg. The facts are fairly readily demonstrable that test animals showed certain adverse physiological effects with the ingestion, say, of 10,000 parts per million in their diet.

Anybody could agree when you sacrifice the animal that is the fact. It is the interpretation to be placed on that, which gets more into the realm, really, of biological and medical statistics.

If a test animal is hurt at 10,000 parts per million of its total diet, may a human still eat the food if it is only in his diet at the rate of 10 parts per million? And it becomes almost, then, a matter of opinion rather than a difference among experts as to the facts. Up until now, as I indicated in my testimony, if there was any harm to test animals which occurred, the Administration felt that, a fortiori, it would be harmful to humans, and out it would go.

Now they say if it is a little harm, well, all right.

What Mr. Gillet was referring to here really, when he said there would be few instances, what he meant was, I feel certain, that when anybody is critical of a food, if a scientist of merit or one who is recognized in his field as a capable fellow says that is a very posionous and deleterious thing to put in your food, it would be a very rare instance where the proponent would be so certain of his correctness that he would, notwithstanding that attack, go ahead and take the necessary legal steps to put the material in the food.

Mr. HESELTON. I am afraid I have exceeded five minutes. I merely want to say I was interested in the statement which was made in which you refer to the differences of opinion, I think if there are differences of opinion, somebody has to resolve them.

Mr. WILLIAMS. Will the gentleman yield?

Because of the fact that this is a subcommittee and not a full committee meeting, unless the committee wishes to, I see no reason why we should adhere to the 5-minute rule.

Mr. HESELTON. I would rather let the committee go ahead.

Mr. WILLIAMS. Mr. Rhodes?

Mr. RHODES. Mr. Coleman, am I correct in my understanding that the Manufacturing Chemists' Association includes the drug manufacturing companies?

Mr. COLEMAN. No, sir. It is composed of the chemical manufacturing companies. The Manufacturing Chemists' Association is composed of such companies as Du Pont, Allied Chemical & Dye Corp., American Cyanimid, Hercules Powder, Atlas Powder, Heyden, and others.

Mr. RHODES. One other question, Mr. Coleman. You mentioned a number of bills, but I do not think you said anything about several others that have been introduced to amend the Food and Drug Act.

Could you give us the views of your organization on these other bills that you have not mentioned?

Mr. COLEMAN. We discussed, as you will recall, in my testimony, the three bills which we felt had the largest number of workable and the least number of unworkable features, as well as H. R. 6747.

The chief other bill before this committee is the bill introduced by Representative Delaney. That bill we would oppose. That bill we would oppose for many reasons, the chief of which is that it does not——

Mr. RODES. What is the number of the one you oppose?

Mr. COLMAN. Could you give me just a second on that?

Mr. LOSER. I think it was H. R. 6747; he opposes that. He said that was more objectionable than any——

Mr. COLEMAN. That is not the bill to which I have reference now. I am referring now not to the Administration bill, H. R. 6747, but Mr. Delaney's bill.

Mr. HESELTON. That is H. R. 7798.

Mr. COLEMAN. H. R. 7798, on the ground it does not, in our opinion, embrace this concept of safety under the conditions of intended use as clearly as do any of the other bills, including the Administration bill, and is also a licensing bill.

It has the bad feature of a licensing bill, and not the good ones of H. R. 6747.

Mr. DINGELL. That applies also to the bill introduced by Mrs. Sullivan, H. R. 7938.

Mr. COLEMAN. I believe that is the same bill.

Mr. RHODES. Thank you.

Mr. DIES (presiding). Mr. Bush?

Mr. BUSH. I have no questions.

Mr. DIES. Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

I understand you oppose the bills proposed by Mr. Delaney and Mrs. Sullivan. Could you give me the reasons for your opposing those bills?

Mr. COLEMAN. Can you give me just a second?

Mr. DIES. I should have called upon Mr. Schenck.

Mr. DINGELL. I would be glad to yield to my good friend.

Mr. DIES. Dr. Neal?

Mr. NEAL. I have no questions at this time.

Mr. DIES. Mr. Schenck?

Mr. SCHENCK. You are going back and forth, are you not?

Mr. DIES. Yes.

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. COLEMAN. Well, first, sir, many of the adverse comments that we made in reference to H. R. 6747, the Administration bill, are equally applicable to the Delaney bill. As I said earlier, many of the provisions in the bill, H. R. 6747, that we would favor, we do not find in the Delaney bill.

It is again, of course, a licensing act, and it does not, in our opinion, as I said earlier, express as clearly as does the Administration bill, H. R. 6747, that the question of safety of any additive is to be determined by examination and a consideration of the intended use of that additive as opposed to any rule-of-thumb basis.

Mr. DINGELL. Mr. Coleman, I do not wish to belabor this point, and I think you have been a most competent witness so far, but I must confess I am not quite satisfied with what you said as being your grounds for opposing the Delaney and Sullivan bills.

Mr. COLEMAN. Well, Mr. Dingell, as another matter, it does not even have the Administration's procedure for handling old additives. It does not have—this bill would apply to all, old and new, without even the Administration's waiting period, sort of a transition period, and so forth.

Mr. COLEMAN. If you should desire, sir, we would be pleased to submit a statement in greater detail, pointing out exactly what our objections to the Delaney bill are.

Mr. DINGELL. That I would appreciate, sir.

Mr. COLEMAN. We shall do so forthwith, sir.

Mr. DINGELL. Good.

(The information referred to was submitted in a letter from Mr. Coleman and appears on p. 145.)

Mr. DINGELL. Let me ask you this question: As I understand, the hearings before Mr. Delaney's subcommittee tended to bring out evidence to indicate that additives which had previously been considered safe are not, in point of fact, really safe. Am I correct in my understanding?

Mr. COLEMAN. I understand there has been some testimony to that effect. I do not know that it established it. I understand there was some testimony to that effect.

Mr. DINGELL. Let me ask you this question, then:

Assuming such evidence were introduced and such evidence were persuasive, and this committee, in its examination of this matter, were to find that such evidence were persuasive, would that, in your mind, be grounds for disregarding this grandfather clause that you have urged upon the committee?

Mr. COLEMAN. Well, don't misunderstand our position, Mr. Dingell. We do not urge at all that any old additive, just because it is an old additive therefore has a carte blanche to be used ad lib in the food supply. We do not say that.

We say that any old additive which has been used can continue to be used until the Food and Drug Administration directs, after appropriate procedures under their act, otherwise.

Mr. DINGELL. Let me ask you this question, and this is something I have not heard any mention of: Certain additives taken once or certain chemicals taken into the human body just on occasion, have no toxic effect; but through use over the years may have a cumulative effect on the body. Am I correct in my understanding?

Mr. COLEMAN. I am not, sir, either a pharmacologist or toxicologist. I am a lawyer. But I understand there is scientific support for that statement, yes.

Mr. DINGELL. What would the impact of such a fact be on your testimony this morning?

I am just asking this; I really do not know. In other words, an additive which may be shown to be safe on, let us say, a 1-shot basis or a 2-shot basis, or maybe a dozen or 50 times, might on the hundredth or the thousandth or the ten-thousandth use be determined to have a bad effect on the human body.

Mr. COLEMAN. Well, may I point out, sir, that the testing, the pretesting provisions of all of these bills, the methodology of that pretesting, there is no effort made in any of these bills to spell it out. That falls within the purview of the Food and Drug Administration after the passage of any one of these acts.

And certainly I feel confident that any regulations they issue or any acceptance or rejection of pretesting data they may employ in the future, will be based on a consideration of both the acute and the chronic toxicity studies that have been conducted.

We recognize, of course, the fact that the pretesting must meet also that problem. The testing itself which has to be done will have to include chronic toxicity studies, which is a phrase I have heard in the past which I believe means the same as that cumulative effect to which you have referred.

Mr. DINGELL. May I ask this question now: I have heard considerable made of the problem of the treating of agricultural fertilizers with pesticides, and things of that sort, as crude additives, and you

mentioned a similar situation as to paint used in a food processor's plant being treated as an additive.

Would you want to make some other comment on that?

Mr. COLEMAN. Well, I am not sure I understand your question, Mr. Dingell.

Mr. DINGELL. Do any of these bills before us treat with pesticides and agricultural chemicals, for example, paints, and other things which are used in the area or which are used on food in its growing stage, something of that sort, would I be fair in expecting that some of those things would be included in any of the bills before the committee this morning?

Mr. COLEMAN. Well, may I say as to pesticides, I think all of the bills make clear that the Miller pesticide amendment of 2 years ago has the effect of being the law for the pesticides and pesticidal residues and, therefore, as such, they are not included within this bill.

As to the agricultural fertilizers, I do not think they fall within the purview of this bill, either, since they are not added to the food.

Mr. DINGELL. Let me cite to you a situation. I do not know whether it would have any point in fact, or not. But a fertilizer or a soil pesticide, for example, to kill, I believe, the things called nematodes, the things that feed on roots, might perhaps be ingested by the plants and ultimately find their way into the food portion of the plant.

What would these bills have in the way of an effect on that kind of thing?

Mr. COLEMAN. Well, I think you will recall in the early part of my testimony I stated that we would strongly urge the amendment, should this committee report out favorably H. R. 6747, the modification of the definition of a food additive to be that material which results or could reasonably be expected to result in its becoming a component of food. And if a soil chemical, through the knowledge scientists have of those things, could be reasonably expected to become a component of the food which results from the plant which grows with the use of the soil chemical, I should think it would fall within the purview of this act.

Mr. DINGELL. In any of these bills, is there provision which would require testing of these fertilizers or of these soil pesticides so that we know whether or not they could reasonably be expected to become a portion of food?

Mr. COLEMAN. Well, in the first place, as to pesticides, as I said before, they are under the Miller Pesticides Act, and Mr. Hitchner—the chairman referred to Mr. Hitchner's statement delivered to you this morning, and I am sure you will find Mr. Hitchner's statement an adequate presentation of the pesticide side of the question, and how that is being handled by the present legislation.

Mr. DINGELL. Does this Miller Act apply to things which are applied to the ground, like soil pesticides and fertilizers?

Mr. COLEMAN. I would prefer that question be referred to Mr. Hitchner, I would be glad to ask him or have somebody else request that he reply to your question, but I would not want to undertake——

Mr. DINGELL. I would not want you to answer something you were not sure of.

Mr. COLEMAN. I would not undertake to answer that.

Mr. DINGELL. The point I want to get at, I want to see to it, if we pass this bill, that the consumer has every protection possible; and if there are some tests that should be required, to see to it that it is applied.

Mr. COLEMAN. I assure you the chemical industry joins in your hope that the American people will be given the greatest and fullest protection.

Mr. DINGELL. Thank you, sir.

Thank you, Mr. Chairman.

Mr. WILLIAMS (presiding). Dr. Neal?

Mr. NEAL. I have no questions.

Mr. WILLIAMS. Mr. Schenck?

Mr. SCHENCK. Mr. Chairman, I have no questions, but I have a lot of questions about the whole subject. It seems to me that this is a question of public health, of individual health; it is a matter which can best be decided by particularly highly qualified internists, and not legal people.

I think we are obligated to consider the effects of additives on persons and people, the cumulative effect. So all this discussion about the technical amendments to the bills at this time leaves me pretty cold.

Mr. WILLIAMS. Will the gentleman yield?

Mr. SCHENCK. That is all.

Mr. WILLIAMS. As the gentleman knows, I am sure, we had intended to have this scientific panel discussion before we got into the technical aspects of the various bills. However, that was impossible, and I will say to the gentleman that we still hope to have the panel in the future, which will clear up the questions which he has in mind.

Mr. SCHENCK. I hope so, too, because I think there is a great field of allergic situations and personal situations which I think may be quite dangerous, affected by additives of one kind or another.

Therefore, I am more interested in the scientific testimony at this time, of qualified internists, than I am in saying that the comma should be put here and a phrase should be added there.

Mr. WILLIAMS. I think that that testimony will be given to the committee in due time. As a matter of fact, the committee wants that kind of testimony.

Mr. Loser?

Mr. LOSER. Mr. Chairman, I am in accord with the statement of Mr. Schenck about the information which we have received. I am greatly interested, of course, in lawyers and that great profession, but I do not feel able to concur in what they would say about matters affecting the public health, although I know they are versatile people.

I was just wondering, Mr. Coleman, if you are familiar with the definition of "safe" as appears in the Sullivan-Delaney bill. Are you familiar with it, without looking at the text?

Mr. COLEMAN. I am afraid not, sir.

Mr. LOSER. You have not studied these two bills, have you?

Mr. COLEMAN. Well, I have asked Mr. Dingell for permission to report on them. We have looked at them, but I have looked at so many, sir, I find it difficult, without referring to the text, to say I am familiar with them.

Mr. LOSER. Of course, you subscribe to the view that it is the duty of the Congress to take every reasonable step available to protect the

welfare and the health of the people of the United States with reference to foodstuffs that go into interstate commerce?

Mr. COLEMAN. Yes, of course, sir.

Mr. LOSER. And if there is any doubt about the safety of a foodstuff, it ought to be resolved in favor of the people and, therefore, discarded; is that right?

Mr. COLEMAN. Well, "any doubt," sir, I think, is an exceedingly broad term. Subject to the judicial review which I have discussed, I certainly feel that the act should be so administered that, in the opinion of experts in the field well qualified, who are employed by the Food and Drug Administration and are available to them, I think the determination of whether or not any material is safe, if made by them, would adequately protect the American health.

Mr. LOSER. But you say in your testimony here that any additive presently used would not be affected by this bill unless the Department should find that it was injurious to the public health and proved by a preponderance of all the evidence. You say that, do you not?

Mr. COLEMAN. I said that any additive now in use would continue to be used unless—it was our proposal that any additive now used could continue to be used unless the Department, for reasons of its own, on its own motion decided to bring it under the procedures of the new bill, and require the same type of determination based on the same facts as these bills would require for a new additive.

Mr. LOSER. But you refer to the preponderance of the evidence with reference to the review, any review of an order issued by the Department.

Mr. COLEMAN. I did suggest that we would feel that the Administrative Procedure Act, which requires only that there be substantial evidence on the record as a whole to support the Administrator, is a little narrow in this field.

May I, as a matter of interest here, state, as you may recall, some time ago the Food and Drug Administration moved against and held hearings to delist, that is, to remove from the list of certifiable colors, certain colors, including Red 32 which had its principal use in the coloring of the outside skins of oranges.

This food color thing, although it is a separate thing, is a situation much similar to what we have in the chemical additives field.

The Administration made an order to delist it. The manufacturers sought the review of that order in three courts of appeal. The manufacturers of the material sought the review in the court of appeals in New York; the Florida citrus growers, who were the customers most directly affected, sought the review in the court of appeals in New Orleans. Some drug companies using the colors sought review in the Chicago court.

Some time ago, the second circuit upheld the Food and Drug Administration; and I learned from Commissioner Larrick this morning that the court of appeals in New Orleans upheld the citrus growers. So now we have the situation where Red 32 for coloring of oranges appears to be illegal in the second circuit, and legal in the seventh circuit.

And it is just that sort of thing which I am sure our amendment, our suggestion that we have it tested by a preponderance of the evi-

dence rather than by a substantial evidence rule, which has been interpreted by some as a scintilla——

Mr. LOSER. In substance, your recommendations with reference to these bills is that there be a hearing de novo on all of these orders issued by the Administrator or the Department.

Mr. COLEMAN. The marked copy——

Mr. LOSER. You can say whether that is right or wrong, and then explain it. That is the substance of what you are saying, is it not?

Mr. COLEMAN. Yes, I suppose; yes.

Mr. LOSER. All right.

Now, go ahead and explain it.

Mr. COLEMAN. Well, I merely want to say as to the proposal we make for the review, we would suggest it be in the district court and that in the district court if, under the usual provisions for permitting the introduction of additional testimony, to wit, it was not adduced below, and there was a good reason why it was not, the district court judge would be permitted to take additional testimony.

To the extent that is a trial de novo, my answer to your question is "Yes."

Mr. LOSER. Well, is it not generally the law of the country where there has been specific jurisdiction conferred upon a quasi-judicial body that their judgment or decree will not be overturned if there is substantial evidence to support the judgment?

Mr. COLEMAN. Well, sir, I think that, as you are well aware, perhaps far better than I, there are countless numbers of cases that deal with the quantum of evidence from a quasi-judicial body that is required to uphold it.

We know what the Administrative Procedure Act provides, and I think there are many who would agree with us, that there is, perhaps, less evidence required to support the Administrative Procedure Act review than almost under any other court review or form of court review.

Mr. LOSER. This present administration bill requires that on a review of its order or judgment that it will be sustained if it is supported by any substantial evidence?

Mr. COLEMAN. They use the language of the Administrative Procedure Act; yes, sir.

Mr. LOSER. Yes.

Wouldn't you think that with a governmental agency charged with the responsibility for preserving or doing what can be done to protect the health of the people of the Nation, that if it feels, with competent help that it has, that this additive should not be used, that that ought to be controlling rather than having a review de novo through the appellate courts of the Nation?

Mr. COLEMAN. Mr. Loser, in my testimony I stated that I thought that the reason it was necessary in this case was because of the emotional appeals that might be brought to bear on the Administrator.

Mr. LOSER. I believe that is all, Mr. Chairman.

Mr. WILLIAMS. Thank you.

Are there any further questions from members of the committee?

Mr. SCHENCK. Mr. Chairman, may I just say further that I certainly intended no criticism or reflection upon the chairman or upon whoever drew up this program as to whom we should hear first.

Mr. WILLIAMS. I understand.

Mr. SCHENCK. But I am deeply concerned and disturbed about the effects of these additives of various kinds on people and, as far as I am personally concerned, that would guide my consideration toward the legislation rather than the convenient phrase or language that would assist in the defense or prosecution of some situation.

Mr. WILLIAMS. I think I can say with reasonable certainly that most of us—are confronted with the same problem, and before these hearings are concluded, we do plan to have this panel of scientific experts here to testify on the physical effects that these additives have on people.

I can assure the gentleman that testimony will be made available before the committee holds executive sessions on the legislation itself.

Mr. SCHENCK. Thank you, Mr. Chairman.

Mr. WILLIAMS. Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

I am sorry to take up the time of the committee, but I just want to ask two questions here.

First of all, why was it that the Food and Drug Administration wanted to decertify this particular orange color?

Mr. COLEMAN. Why did they do it?

Mr. DINGELL. Yes.

Mr. COLEMAN. Well, the evidence at the hearing before the Food and Drug Administration indicated that when this color was fed in gross quantities, large quantities, far in excess of any possibility, far in excess of any quantity that could possibly be expected to be ingested by human beings, there were adverse physiological effects on the test animals.

Mr. DINGELL. Wasn't it actually a carcinogen or cancer breeder?

Mr. COLEMAN. There was no evidence at all to support that statement.

Mr. DINGELL. I just wondered.

Mr. COLEMAN. Nor does Mr. Larrick himself believe—he has indicated that he felt that under the conditions of use, these colors are harmless.

The Administration's position is that since the law does not impose, as a test for food colors or for other additives, the concept of "harmless under the conditions of intended use," but merely says harmless that if the color or additive—if it is capable of being used so as to produce harm, irrespective of the level, that therefore it may not be used under the present language of the law. But there was no evidence of the——

Mr. DINGELL. Another question, then:

Was there a trial de novo in either instance?

Mr. COLEMAN. On any of these food colors?

Mr. DINGELL. On this particular case that you told us about this morning, this Red 32.

Mr. COLEMAN. No, there was not.

Mr. DINGELL. It was a test under the Administrative Procedure Act?

Mr. COLEMAN. That is so.

Mr. DINGELL. Based on the substantial evidence test; am I correct?

Mr. COLEMAN. That is so.

Mr. DINGELL. And two courts arrived at a different result?

Mr. COLEMAN. That is so.

Mr. DINGELL. And it took about how long to arrive at this result?

Mr. COLEMAN. Well, it is difficult for me to say.

There was also the matter, I believe, that is still pending before the Court of Appeals in Chicago, in which no result has been reached yet. It is a matter of some years.

Mr. DINGELL. Approximately how long has it been since the matter was first brought up by the Food and Drug, and how long since the Food and Drug first made its original findings?

Mr. COLEMAN. Excuse me, sir.

Mr. SCHRAMM. I believe, sir, it was in the neighborhood of March 1956.

Mr. DINGELL. Would you give your name, sir?

Mr. SCHRAMM. Mr. Arthur Schramm, national aniline division, Allied Chemical & Dye.

Mr. DINGELL. How long?

Mr. COLEMAN. Mr. Dingell, I am afraid that was not when the thing started.

Mr. DINGELL. Would you furnish it for the record?

Mr. COLEMAN. We will submit that information to you, yes, sir; the exact dates.

(The information requested was supplied in a letter from Mr. Coleman and appears on p. 145.)

Mr. DINGELL. The reason is, it appears on the basis of what your testimony is this morning, that this is not any hurry-up, rush procedure.

Mr. COLEMAN. I cannot hear you, I am afraid.

Mr. DINGELL. On the basis of what you told us this morning it appears that this procedure under the Administrative Procedure Act, substantial evidence test, is not any hurry-up procedure which would have stampeded the food processors and manufacturers in any disorderly fashion.

It also appears it is possible for an extremely favorable result to the industry, because two circuits can come to a different conclusion; am I correct?

Mr. COLEMAN. I have not had an opportunity of reading the opinion of the New Orleans court, but certainly I was advised by the Commissioner this morning—I had not heard it, since the opinion only came down yesterday—that they, the Food and Drug Administration, had lost.

Mr. DINGELL. But, on the basis of your testimony, it would appear that there is a possibility of an extremely favorable interpretation for the industrial user. The point I make is that no inference against fairness of the substantial evidence is possible on this particular case.

Mr. COLEMAN. It is always possible, certainly, that you can win a lawsuit.

Mr. DINGELL. No further questions.

Thank you, Mr. Chairman.

Mr. WILLIAMS. Any further questions?

Mr. Coleman——

Mr. COLEMAN. Yes, Mr. Williams.

Mr. WILLIAMS (continuing). Before he left, Mr. Heselton asked me to have you clarify for the record your reply to one of his questions in which you mentioned the 5-year period before this law would take effect. Did you make reference to the 5-year period with respect to all

additives or just new additives? Would you clarify what you meant by that 5-year period?

Mr. COLEMAN. Well, the 5-year period, sir, is a suggested modification, to be accomplished by adding 3 years to the 2-year period set forth on page 16 in the Administration's bill, H. R. 6747——

Mr. WILLIAMS. What does that make reference to?

Mr. COLEMAN. Page 16, line 21 of H. R. 6747 which, in its present form, gives the Secretary the discretion, in effect, to extend for 2 years after the effective date of this bill the existing law as to old food additives.

Mr. WILLIAMS. I see.

Mr. COLEMAN. This proposal would be that the Secretary be given that discretion for 5 years.

Mr. WILLIAMS. Then the answer, of course, would be that that period would apply to old food additives or additives which had been in long use?

Mr. COLEMAN. In the Secretary's discretion.

Mr. WILLIAMS. Yes, sir.

Mr. Coleman, I assume, from the answers that you have given to questions of the committee, that you are a lawyer?

Mr. COLEMAN. Yes, sir.

Mr. WILLIAMS. Of course, because of the line of work that you are in, I assume that you are generally familiar with the Food and Drug Act, as it stands?

Mr. COLEMAN. Yes, sir.

Mr. WILLIAMS. With respect to that, would you tell us whether or not, in your opinion, the problem that we are confronted with with respect to new food additives or new chemical additives is similar to the new drug problem or the pesticide problem?

Mr. COLEMAN. I would say, yes, it is similar.

Mr. WILLIAMS. Well, now, going on then, would you say, by the same token, that the law with respect to new chemical additives should more or less conform to the procedures used in the law with respect to new drugs and pesticides?

Mr. COLEMAN. I do not think that the similarity is such as to demand complete uniformity of treatment.

Mr. WILLIAMS. Would you first let me ask you, for purposes of information, what you would consider the differences to be, the practical differences?

Mr. COLEMAN. Well, in the first place, a drug, by its very nature, is recognized generally as being, in the quantity that it is possible for a human to ingest, a poisonous, injurious substance. Aspirin certainly we know to be capable of harm, yet we also know that it certainly should be permitted to be sold, and is sold, because it is also capable of great good. I use that as an example.

So that a drug starts off with the presumption that it is potentially a harmful thing, but that it should be used because of the good that it does.

Therefore, the law, under the new drug section, is tailored to that factual situation.

Now, the great bulk of chemical additives are not material so classified. And to put them, to cast the new chemical additive or food additive legislation, in terms of the new drug legislation would have

the effect of giving a presumption to any proposed additive that it is a substance capable of causing adverse harm to human beings, which just is not the case. It is a different sort of thing.

Mr. WILLIAMS. As I understand it, the distinction you make is that you feel these food additives should be given the presumption of harmlessness in the beginning, and that the harmfulness of them should be proven——

Mr. COLEMAN. Well, Mr. Chairman——

Mr. WILLIAMS (continuing). As contrasted with the new drug theory?

Mr. COLEMAN. I would think that is so.

I hesitate to get into a technical discussion in this as to what presumption should apply and what should not, from a legal point of view, but I think the chairman has summed up my view exactly, and the pesticides fall within the same general category as the new drugs. They are designed to kill things.

Mr. WILLIAMS. Well, is that distinction basically the difference between the approaches made in the bills which you favor and the approach made in the bills you do not favor?

Mr. COLEMAN. I think that is the reason for the distinction, the reason we feel there is no need for uniformity of legislation between the Miller pesticide amendment, the new drug section, and the proposed food additive section.

Mr. WILLIAMS. Well, briefly, could you give us the differences between the procedures in the bills that you suggest and those followed in the new drug and pesticide acts?

Mr. COLEMAN. I would prefer, if the chairman would permit me to, to again file a memo on that. There are rather technical differences that I do not feel, without having them before me this morning, that I would be equipped to answer.

Mr. WILLIAMS. Well, if it is not too much trouble, I think the committee would like to have that information.

Mr. COLEMAN. We can get it for you quickly.

Mr. WILLIAMS. A comparative analysis, if you want to call it that, is what we want.

(The information requested was submitted in a letter from Mr. Coleman and appears on p. 145.)

Mr. WILLIAMS. You stated your opposition to licensing——

Mr. COLEMAN. Yes, sir.

Mr. WILLIAMS (continuing). Of these new additives.

Would you explain exactly what you mean with respect to the licensing of new additives. I think most of us understand it, but for the sake of the record, would you explain that, and why, in your opinion, the administration bill calls for licensing, and the industry bills do not?

Mr. COLEMAN. Why, certainly, sir.

Mr. WILLIAMS. Why you take issue with that particular feature.

Mr. COLEMAN. Under the Administration bill, H. R. 6747, the proponent of a new food additive must, leaving aside now for the moment all questions of pretesting and review and other questions, he must ask the Food and Drug Administration for permission to use an additive in food.

Without the approval of the Food and Drug Administration, without its stamp of approval, its imprimatur, that additive may not be

used under the provisions of the Administration's bill. The license may be granted or it may be denied.

It may be denied for sound reasons. It may be denied arbitrarily, but it still would be denied.

Under our procedure, the proponent of a new food additive would give to the Administration the same advice that would be given them under the Administration's bill, but under our procedure, the proponent of the new food additive would say to the Administration not, "May I use it?" but he would say, "I am going to use it, unless you see fit between now and whenever I advise you I am going to use, it, to stop me."

Mr. WILLIAMS. Well, that, in effect, ties in with the philosophy you just expressed with respect to presumption.

Mr. COLEMAN. That is so.

Mr. WILLIAMS. And the licensing would put the burden of proof on the manufacturer or the user of the additive to show it was harmless rather than on the Food and Drug Administration to show it was not.

Mr. COLEMAN. I think the practical effect would be just that, sir. However, you recall, under all the bills, the basic evidence that is required to make that determination would be submitted by the manufacturer to the FDA.

Again we come to the question of interpretation of scientific data. I was not suggesting in any way, in answering your last question, that we would place the burden of determining the pharmacological and toxicological information on the FDA alone, not by any manner of means.

Our bill requires the furnishing of the data, just as does, and in the same language as, the Administration's bill.

The evidence on which they would support or not be able to support the burden of proof would be evidence that the proponent gave them, together with whatever else they wanted to get.

Mr. WILLIAMS. Several of the bills provide for an advisory committee with respect to making these determinations. Do you feel that this legislation would be the proper place for an advisory committee?

Mr. COLEMAN. Speaking on behalf of the chemicals-in-foods committee of the Manufacturing Chemists' Association, I must say that we discussed that very question in our last two committee meetings; and we felt, the majority of the members in that group felt, that this is not a proper place for an advisory committee; because we feel, the majority of that group felt, that the advisory committee substitutes an extralegal judge in between the two opponents, the true opponents, if it is an adversary proceeding, or in a friendly proceeding, which most of them are, these two parties being the Food and Drug Administration and the proponent of the food additive.

There is no opportunity given to cross-examine the members of the advisory committee. A subpena power does not exist under the proposal for calling the advisory committee, to make possible calling these persons as witnesses.

As lawyers—many of us are lawyers on that committee—we opposed the concept of this extralegal thing.

We recognize, however, the value of the advisory committees.

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We recognize that industry has, and industries very close to us have, supported in the Miller Pesticide Act, the use of an advisory committee, and we know there are very many arguments in favor of it.

We have, as a matter of fact, in our marked copy of H. R. 6747 given you proposed modifications that we would feel necessary to the advisory-committee sections of the Administration's bill.

But I think, speaking for a majority of our group, that we feel this is not the proper place for an advisory committee. We feel advisory committees are something apart from the proper administration of a law of this nature, and that we should be left to the usual methods of decisions of this kind.

Mr. WILLIAMS. What procedure do you suggest for the Food and Drug Administration to follow to get their expert advice on whether or not they should take action to prohibit the use of an additive or to grant it?

Mr. COLEMAN. Well, I am certain that the chairman is well aware of the fact that some of the outstanding men of knowledge in the field of pharmacology and toxicology, properly equipped to make the decision as to the safety under intended use of any food additive, are on the staff of George Larrick and the Food and Drug Administration.

They themselves have the knowledge. There are only a relatively few people comparably qualified outside that staff—there are many, but the numbers are relatively few, compared with the great numbers that there are on that staff.

Mr. WILLIAMS. You referred to the relative concept of safety in your statement.

Mr. COLEMAN. Yes, sir.

Mr. WILLIAMS. That is the matter of taking these additives in quantity or taking them in small doses. In one case it would be dangerous and in the other case it is perfectly harmless.

In cases where experts or scientists disagree with respect to the amounts of those additives which would create harm, and there is honest disagreement among the experts in those fields, in that case do you feel that the presumption should be indulged in favor of the additive or against the additive?

Do you feel that the additive should be kept off the market until a final determination has been made or do you feel that it should be used in lesser quantities than agreed upon as being dangerous?

Mr. COLEMAN. I am sure the chairman is aware of the fact that when we were discussing this question of quantitation, we were discussing it in very small amounts.

I am sure also that the chairman is aware of the fact that both the Food and Drug Administration and industry have recognized that very problem which you mentioned, and we all are aware that if and when the Administration, under the provision of its bill or any of the others, permits or does not oppose the use of the new food additive in certain quantities in any food, that there will be built right into that tolerance regulation a safety factor which would well overcome, I believe, any minor differences of opinion there might be among experts.

For instance, if one expert said that at 500 parts per million, this material would be harmful to humans, and another expert says, "Oh, no, 300 parts per million would be harmful to humans," it would be my thought that in a situation like that, and in any similar situation, the imposition of a safety factor would mean that the Food and Drug

Administration would say, "In no event could that material be used in more than 50 parts per million."

So the difference between 300 and 500, if that difference existed, would disappear in a minute in view of the safety factor, and I am sure the FDA would impose such a safety factor on any of these additives.

Mr. WILLIAMS. Mr. Coleman, what would be your position with respect to approval of an additive by the Food and Drug Administration in this case:

Do you feel, after it has once been approved, it should be made available for use by anyone in the same quantities in which it was approved or do you feel that the approval should apply with respect to the one particular manufacturer who sought its approval?

Mr. COLEMAN. That is a most delicate and difficult question to answer, and one which I do not think is properly met by any of the bills.

It is one, I am sure, which would have to be worked out with the Administration.

I should certainly think that arguments could be readily made on both sides. One argument would be: The man who spends the money to do the pretesting, he should be entitled to the permission to use that material, and nobody else, none of his competitors, should be permitted to ride on his coattails.

On the other hand, if an additive has value, and any man can make it, and the FDA licenses it, everybody who can make it, without violating the laws of the country, should be permitted to do that, sir.

However, this points up one of the evils of a licensing bill, although it also has some facets in the injunction procedure, it points up one of the evils of a licensing bill: to whom do you grant the license after the application has been made by one? It has all sorts of overtones which we have thought through at the time about the possibility of monopolies being built up in any particular field where a fellow has an FDA license, and so forth, which, I think, could be avoided if H. R. 8390, the philosophy of that bill, were adopted, and if FDA were left with the classical methods of enforcement of its powers.

Mr. WILLIAMS. Can you tell me how that problem is met with respect to new drugs and pesticides?

Mr. COLEMAN. My understanding of that is—and again I would prefer that the questions in relation to pesticide chemicals be answered by the trade association representatives who are familiar with it, the National Agricultural Chemical Association.

However, I believe I am right in saying that once a tolerance is fixed for any particular pesticide, that the tolerance is fixed for that pesticide, and subject, of course, to patent rights, anybody can then sell it, with the instructions on the label that that is the maximum quantity that can be found on the raw agricultural commodity.

Mr. WILLIAMS. Do I understand the answer you gave to the first question, about your position with respect to that, to be that your organization is willing to leave that up to the committee's judgment completely, and that you take no position with reference to whether or not it should be made an across-the-board authorization or whether it should be limited to the applicant?

Mr. COLEMAN. Well, I would think that was the sort of thing that the Food and Drug Administration could properly—it would be one

of the things they worried about when they were writing their regulations.

I speak not for a unanimous group, but the bulk of the people in our group felt that to burden the bill with that type of thing before the Administration had a fair chance to work it out themselves, and they have full recognition of the problem, would, perhaps, be unnecessary.

Mr. WILLIAMS. Are there any further questions?

Mr. HESELTON. Mr. Chairman.

Mr. WILLIAMS. Mr. Heselton.

Mr. HESELTON. I noticed with a good deal of interest your emphasis on what you characterize as licensing.

You said in your statement that H. R. 6747 is essentially a licensing bill.

You refer to it later, I think, as the basic defect in the law.

I was not aware of the fact that any great objection had been raised to previous bills on the ground that there was an attempt to vest in the Food and Drug Administration the power to license in the statement I read and which I have reviewed again, the statement by Mr. Gillet in 1956.

In the five basic principles Mr. Gillet gave us, and which you repeated this morning, he said, No. 3, was:

> That the manufacturer must bear full responsibility for his own compliance with the law, but that no man should be his own referee as to safety and the adequacy of testing for safety.

Mr. COLEMAN. Yes, sir.

Mr. HESELTON. It may well be that you brought out that distinction while I was out of the room. But I wonder why all this emphasis on licensing, as a basic defect, without any previous reference, as I understand it, to that objection?

Mr. COLEMAN. Well, first, if I may address myself to the first half of your question, Mr. Gillet's statement, which appears at page 113 of the hearings of the last session that the manufacturers bear full responsibility for their own compliance with the law, but that no man should be his own referee as to the safety and the adequacy of testing for safety——

Mr. HESELTON. You repeat it in your statement on page 5 today.

Mr. COLEMAN. Yes.

In saying that "no man should be his own referee," Mr. Gillet meant last year, and I meant, when I repeated it this morning, that neither the FDA nor the manufacturer should be the referee, and that it was up to the courts to decide whether or not the man, whoever the proponent was, had properly lived up to the law.

We recognize also that this means the manufacturer should not be his own referee, but this does not imply licensing. This does not imply licensing at all.

This says that the Administration—if the FDA disagrees, the FDA can get the referee, the classical referee, the court, to make the determination.

Mr. HESELTON. Specifically, where is the licensing provision in H. R. 6747?

Mr. COLEMAN. 6747?

Mr. HESELTON. Yes.

Mr. COLEMAN. The specific provision will be found on page 5, line 6, of the subtitle "Petition To Establish Safety."

Mr. HESELTON. That is subsection 409 (b)?

Mr. COLEMAN. Yes.

Mr. HESELTON. How much of that do you say involves licensing? All of it?

Mr. COLEMAN. Well, that entire section, and the entire following section, beginning on page 6, line 19, and the section beginning on line 11 of page 9.

It says, in effect, that the proponent petitions for permission to use—that is, the petition contains certain things, in the subsection beginning at line 19, page 6.

It says what the Secretary does with his petition.

Mr. HESELTON. Then you say that everything beginning with line 6 on page 5 through line 2 on page 10 involves licensing?

Mr. COLEMAN. That is so, sir.

Mr. HESELTON. Were those sections in the bills that were before the committee in 1956?

Mr. COLEMAN. You will recall that this is the first time that the administration has put in a bill.

The bill on behalf of which Mr. Gillet was testifying last time was the then pending O'Hara bill, and the administration had not proposed this licensing method, although the industry was well aware that the administration favored that method.

Mr. HESELTON. That is not my question. My question is: Was any part of the provisions to which you just referred in H. R. 4475, H. R. 7605, H. R. 7606, H. R. 8748, H. R. 7607, H. R. 7764, H. R. 8271, or H. R. 8275 before the committee in 1956?

Mr. COLEMAN. Those provisions of the bill, which would require pretesting by the proponent were included.

Mr. HESELTON. Did that involve licensing?

Mr. COLEMAN. Pretesting by itself certainly does not.

Mr. HESELTON. Were any of what you are objecting to, were any portions of the bills that you characterize as licensing, in any one of those eight bills before the committee in 1956?

Mr. COLEMAN. Mr. Gillet, representing us, did not comment on any bills——

Mr. HESELTON. Now, Mr. Coleman, you are a lawyer, and you understand my question.

Mr. COLEMAN. I understand your question. You did not quite let me finish.

As to the other bills that were pending before the committee at that time, I am afraid I would be unable to answer whether or not they contained a specific provision which we would here denominate as licensing, or a philosophy which we would here denominate as licensing.

I would be very happy to advise you subsequently, after those bills are restudied, whether or not that is the fact.

Mr. HESELTON. The fact remains that your association, represented by the chairman of the chemicals in foods committee, testified before the committee on all these bills in 1956, and I do not find one word in that testimony referring to licensing or any proposal of licensing.

What I am interested in is some explanation as to why you criticize the bill introduced by the chairman of the committee for proposing licensing and as a basic defect in your statement today.

It is not new; is it?

Mr. COLEMAN. I must say that I believe, perhaps, you and I are putting different interpretations on Mr. Gillet's testimony of last year.

He testified only in favor of those bills which were the injunction bills and the declaratory judgment bill.

He was not—at that time, apparently either the bills that were pending before this House did not have the licensing provisions as they now contain, or it was not felt that comment should be made upon them by that witness.

The Manufacturing Chemists Association has classically, ever since we first entered this field, and ever since we first knew about the proposed legislation, we have uniformly in all our public announcements to groups around the country, to bar association groups and others, we have uniformly opposed any concept of licensing.

Mr. HESELTON. The bells have rung, and I want to be fair to you.

I wish you would read Mr. Gillet's testimony. I note hurriedly that he referred to a number of bills. I assume that he referred to most, if not all, of the bills pending before the committee.

If some of those bills contained the provisions you have said are contained in the bill filed by Mr. Harris in H. R. 6747, what I would like to have you do is to furnish a supplementary statement——

Mr. COLEMAN. I certainly shall do so, sir.

Mr. HESELTON. As to why there was not some objection addressed to the committee in terms of licensing proposals.

Mr. WILLIAMS. Will the gentleman yield to me?

Mr. HESELTON. Yes, sir; I would be glad to.

Mr. WILLIAMS. In that regard, Mr. Coleman, there are any number of phases of this legislation that we have not touched upon in our interrogation of you and, because of your position in the industry, I am quite sure that the committee would like to have an opportunity to interrogate you further at some later date.

Mr. COLEMAN. Certainly, sir.

Mr. WILLIAMS. I am wondering if it would be agreeable to you if you might appear before the committee at some later date that would be mutually agreeable to you and the committee?

Mr. COLEMAN. I shall be happy to do so, and will await your call.

Mr. WILLIAMS. There are questions dealing with the subject of these incidental additives, questions dealing with the functional value, which have not been touched upon, and quite a number of other phases.

Mr. COLEMAN. Certainly, sir.

Mr. HESELTON. Mr. Chairman, would it be agreeable if Mr. Coleman would furnish the answer to the question I asked before we arrange for him to come back?

Mr. COLEMAN. Certainly; I will do it just as quickly as we can, Mr. Heselton.

Mr. HESELTON. Thank you.

(The information referred to follows:)

MANUFACTURING CHEMISTS' ASSOCIATION, INC.,
Washington, D. C., July 29, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: In the course of my testimony before your committee on July 17, I requested permission to submit, for incorporation in the record of your hearings, answers to certain questions raised. Reference is made to pages 172–173, 189, 194, and 207–208 of the transcript of the testimony.

1. At pages 172–173, I was asked to state the position of the Manufacturing Chemists' Association with respect to H. R. 7798. Our association has not formally adopted a bill-by-bill position on each of the many food additive bills that have been introduced in this and prior years. In essence, our association has done two things: First, both Mr. Gillet's testimony last year and my testimony this year outlined the principles which we believe constitute, as I said, "a sound basis for congressional action" in this field. The association is for the bills based on these principles, and opposed to the bills not based thereon. Second, as stated in my testimony on July 17, in the light of these principles, effort was made to weigh the good features of the various bills, as we see it, against the unworkable or impracticable features—and, as I went on to say, "Weighing the good features of the various bills against the unworkable or impracticable features, it is the opinion of our association that the bills which have the greatest number of good features, and the least number of features calling for amendment, are the bill introduced by Chairman Harris, H. R. 8390, the companion bill introduced by Representative Wolverton, H. R. 8629, and the bill introduced by Representative O'Hara, H. R. 366."

What this means in terms of H. R. 7798 is simply this: Since it is a licensing bill, it is a bill to which we are opposed, in the light of the basic principles set out in the association's testimony both this year and last. Moreover, H. R. 7798 appears to be based on what we regard as the erroneous concept that some substances are, and others are not, "poisonous" or "deleterious." Our association approves of that part of the approach taken by the administration bill, H. R. 6747, which deals with the safety of an additive in terms of the amounts and the conditions proposed for the use of the additive. It is felt that H. R. 7798 would represent a backward step in that it would tend to perpetuate the "poisonous per se" concept, and thereby would reject all that has been learned through the modern science of pharmacological analysis and toxicological testing. H. R. 7798 also requires that an additive must be "approved" by the Secretary as "useful to the consuming public." As was pointed out, our association feels that legislation in this field should deal with the safety of the additive—and should not grant the Secretary of Health, Education, and Welfare the power to prohibit the use of an additive on the basis of his belief as to its "usefulness" or "functional value." For the foregoing and other reasons touched upon in the oral testimony, the association does not believe that H. R. 7798 meets the very real need for a modern and workable statute which exists in this field.

2. At page 189, I was asked to submit for the record certain dates with respect to the delisting of Red 32. The chronology of the Red 32 proceedings can be summarized as follows:

December 19, 1953: Notice of hearing to delist Red No. 32, and Orange No. 1 and No. 2 appeared in Federal Register.

January 19, 1954: Hearing held before FDA.

December 30, 1954: Tentative delisting order published in Federal Register.

November 16, 1955: Final order effective February 14, 1956, published in Federal Register.

February 7, 1956: Petition for review filed in United States Court of Appeals, Second Circuit.

August 10, 1956: Secretary's order affirmed by United States Court of Appeals, Second Circuit.

3. At page 194 of the transcript, I was asked to summarize the differences in the procedure under H. R. 8390 and under the new drug and pesticide acts. Since the date on which I testified, Mr. Austern has ably presented to your committee not only the differences in these procedures, but also the reasons for these differences. I had also touched upon the reasons for these differences in my testimony

on July 17, 1957, so I shall not attempt to repeat here those matters which, in our opinion, have been adequately covered by others. However, in terms of the question that was addressed to me—the actual procedures which apply in the case of a new drug, a new pesticide, and a new food additive (under the provisions of H. R. 8390)—the situation can be summarized as follows:

	New drug	New pesticide	New food additive (H. R. 8390)
Means whereby Food and Drug Administration enforces its views.	Administrative order approving or disapproving the new drug; can be appealed to district court.	Administrative regulation setting a tolerance for the new pesticide; can be appealed to court of appeals.	Administrative decision; in case of disagreement, temporary restraining order issued by district court, followed by district court proceeding for permanent injunction. (Procedure follows the standard pattern that applies to other Food and Drug Administration proceedings, not including new drug and pesticide proceedings.)
Exemption for substances in prior use.	Yes	No	Yes.
Court where judicial review takes place.	District court	Court of appeals	District court.

4. At pages 207–208, I was asked to explain why Mr. Gillet's testimony last year did not contain "some objection addressed to the committee in terms of licensing proposals." Mr. Gillet's testimony last year, as my testimony this year, dealt primarily with the principles which the association feels should be enacted into law. Both Mr. Gillet and I testified that, in the opinion of our association, there is a need for legislation in the food additives field. At the time that Mr. Gillet testified, the Administration had not proposed a bill of its own, and although the Administration had informally indicated that it desired the licensing approach, it did not appear to be the occasion to explain our association's opposition to the licensing approach. Opposition to licensing legislation in this field, I might add, has been expressed publicly by our association on many occasions, both before and since the 1956 hearing. When Mr. Gillet appeared before your committee, however, he was addressing himself solely to the type of policing legislation which our association is for, as contained in bills which had been introduced by Chairman Priest and Representative O'Hara. Accordingly, in Mr. Gillet's testimony before your committee he discussed only 4 bills—2 declaratory judgment bills and 2 injunction bills. None of these bills contained the objectionable licensing feature which the Administration has now proposed.

It should be pointed out in this connection however, that in Mr. Gillet's letter to your committee following his testimony (1956 hearings, p. 117) he emphasized that the bills recommended by our association—the Priest-O'Hara bills—"would give FDA added authority which it does not now possess—and would give FDA this *added authority in a framework that is consistent with FDA's traditional policing role* in the food field." [Emphasis added.] Obviously, the only reason for mentioning the "policing role" of FDA was to distinguish this role from the "licensing role" which FDA has now proposed—and which it was generally recognized, in 1956, that FDA favored, even though FDA was not formally sponsoring any specific legislation at that time.

I hope that the material set out above will be of assistance to your committee in connection with the questions addressed to me when I appeared before you on July 17. In accordance with the request which you made on that occasion, I stand ready to appear before your committee again at whatever time you wish.

Sincerely,

LAWRENCE A. COLEMAN,
Chairman, Chemicals in Foods Committee, Manufacturing Chemists' Association, Inc.

Mr. WILLIAMS. The House is now in session, and this afternoon it is considering the Mutual Security Act of 1957 under the 5-minute rule for amendment, and therefore, it would be impossible for the committee, under the rules of the House, to sit during the afternoon.

I wish to thank you, Mr. Coleman, for the testimony that you have given, for your direct replies to questions that have been propounded, and I feel that your testimony will be of great value to the committee.

We had one more witness scheduled for this morning, Mr. Jerome Heckman, representing the Society of the Plastics Industry and we regret that we will not be able to hear him today.

However, I have instructed the staff to try to arrange with him a date at which he may appear later to give his testimony to the committee. I regret very much those circumstances exist.

According, the committee stands adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 12:10 p. m., the committee recessed, to reconvene at 10 a. m., Thursday, July 18, 1957.)

FOOD ADDITIVES

THURSDAY, JULY 18, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334, New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. This morning the committee meets to receive further testimony in regard to the problem of food additives.

Before I call on our first witness, I would like to make this statement: Mr. John Kuniholm was scheduled to appear yesterday on behalf of the Society of the Plastics Industry. I am sorry he could not be reached yesterday. The morning was consumed with the testimony of Mr. Coleman, of the Manufacturing Chemists' Association.

Mr. Kuniholm has requested that his prepared statement be inserted in the record at this point, and he has further requested that he be given an opportunity to summarize his statement orally at a later date.

At this point in the record Mr. Kuniholm's prepared statement will be inserted, and he will be notified when a date for the continuation of hearings will be set.

(The statement referred to is as follows:)

STATEMENT OF JOHN G. KUNIHOLM ON BEHALF OF THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

Mr. Chairman and members of the committee, my name is John G. Kuniholm. I am appearing on behalf of the Society of the Plastics Industry, Inc., as chairman of the society's food-packaging-materials committee.

The Society of the Plastics Industry, Inc., was formally organized and incorporated in the State of New York in 1937. Its present membership comprises companies responsible for approximately 85 percent of the plastics industry, dollar-volume-wise. By far the majority of the member companies are properly classed as "small businesses" engaged in the manufacture of plastic materials and the fabrication of finished products therefrom. The society seeks to disseminate scientific, engineering, and other information on plastics and generally to advance the application and use of plastics.

The use of plastics in food distribution, and specifically plastic food containers and plastic films for wrapping, is a vital and integral part of food manufacture, distribution, and retailing. A visit to any modern supermarket immediately reveals the role that plastics play in the packaging of meat, vegetables, and all other foodstuffs. The activities of the plastics industry in the food-packaging field are broadly referred to as the plastic food-packaging industry. That this industry attaches major significance to the pending legislative proposals with respect to food-additives legislation is evidenced by the formation on March 1, 1957, by interested members of the society of a committee on food-packaging materials to investigate and evaluate legislative proposals to regulate chemical additions to food.

After study of the various legislative proposals, the committee made recommendations to the governing body of SPI, and on June 28, 1957, the board of directors of the Society of the Plastics Industry, Inc., unanimously adopted the following resolution:

"*Resolved*, The board of directors of the Society of the Plastics Industry, Inc., endorses and approves the philosophy of 'notification' in food additives legislation. By 'notification' is meant the establishment of procedures whereby the proponent of a new food-packaging material may ship it for use without the prior approval of the Food and Drug Administration upon the expiration of a suitable period after the submission of data showing that such material is safe for use under the conditions of use."

The plastic food-packaging industry points with pride to the advance in food distribution through the development of packaging materials made with plastic. New methods of packing have, in fact, led to a degree of public protection from bacteriological contamination of food to an extent impossible before the advent of the newer types of containers and wraps. We feel that our industry has an extraordinary record of providing the public with the most advanced safeguards in the world insofar as cleanliness and sanitation in the distribution of food products is concerned.

In view of this record and the existing law[1] regulating any possible contamination of a food resulting from its package or container, we are not convinced that all of the provisions of some of the present bills before your committee need, from a public health point of view, have applications to packaging materials. The apparent primary object of these legislative proposals is to prevent possible harm to the health of consumers arising from the use of chemicals as food ingredients.

However, a majority of the bills before your committee, Mr. Chairman, define "food additives" in such a way as to include packaging materials which are not deliberate food additives and which are not intended to alter any quality or property of food. The packaging component, which may on occasion constitute an incidental additive, is not primarily intended to become a part of the food, and its presence in food is rare. Under the circumstances, it would appear that if, after an investigation, FDA finds that the container or package is composed of a substance which may render the food injurious to health, it has adequate powers under section 402 (a) (6).

We advocate enactment of H. R. 8390, the second bill introduced by your chairman, or a similar measure. That bill formalizes the existing industry practice under the act and frees industry from the academic per se rule. It makes mandatory the advance submission of pretesting data to the FDA prior to the marketing of new substances and gives FDA adequate opportunity to enjoin food use of any substances which have not been shown to be safe for use under the conditions of use. This bill gives legal sanction to existing informal practices between the members of the industry and the FDA. At the same time, it imposes uniform requirements on all members of the industry concerned.

The second Harris bill (H. R. 8390) is in our view superior to the so-called FDA proposal embodied in H. R. 6747, the first bill introduced by Mr. Harris. This is clearly evidenced when the bills are compared in the light of the three most controversial issues which have arisen on the subject of food additives legislation.

1. *Policing versus licensing.*—The licensing philosophy of food additives legislation is premised on the belief that new food uses of chemicals are suspicious and that chemical additions to food, however they may occur, are presumptively unsafe. Adoption of this philosophy would require the proponent of new uses of chemicals in connection with food to prove that they are not unsafe and that, even when so proved harmless, their use should be only in accordance with a detailed regulation. Such regulations would specify allowable uses, permissible tolerance levels, mandatory labels, etc.

As an alternative, we support the proposal in H. R. 8390 and similar bills for pretesting and notification. Advance submission of pretesting data to the Food and Drug Administration, coupled with notification of intent to use new additives or food-packaging components, gives all the protection that preapproval under a

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[1] "SEC. 402. A food shall be deemed to be adulterated—

* * * * * * *

"(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."

licensing bill insures. This approach gives the Government authority to act if it has real reason to seek to prohibit the use of chemical additives.

H. R. 8390 properly recognizes the realistic factual setting in which food-packaging components, as well as direct chemical additives for food, are developed. The presence of chemical additives in food does not automatically create a risk or hazard to the public health. Rather, it creates only the occasion for determining if a risk exists. In many instances the additive will be harmless because it is as nontoxic as water or because of its insignificant quantity. In the case of packaging components, the possibility of risk is even more remote, comparatively speaking, since, on the basis of experience, few packaging components migrate to food in any significant quantity.

It is entirely unwarranted to contend that new packaging components should be considered prima facie unsafe. No legal presumption against safety should be indulged. Although it is only commonsense to evaluate the safety of new food additives and packaging components—and this is the accepted practice today in our industry—this provides no reason for creating a continuing legal presumption against new products or materials. A commonsense evaluation, as provided by measures such as H. R. 8390, will protect the public without unnecessarily burdening industry or the Government.

2. *Grandfather clause.*—Although both bills contain similar clauses, we merely wish to point out the historic legislative policy which disfavors retroactive legislation. Should some evidence pointing to a hazard resulting from the use of existing additives be uncovered, the present law gives FDA adequate power to halt its use. Here again, however, we wish to voice our support for H. R. 8390 because of its realistic and plain recognition that FDA has in the past granted sanctions of new packaging components on an informal basis and that components so approved should be considered exempt from the requirements of the new law.

3. *Functional value test.*—For all of the reasons which have been previously given, the law is designed to establish safety only and not give FDA power to determine the functional value of a packaging component. The American consumer should be the final arbiter of what is useful in a free society.

In the light of these and other considerations, we wish to reaffirm our endorsement of H. R. 8390 and similar measures.

There is only one major amendment which we suggest for your consideration. It relates to the inclusion of "food additives" (which term includes packaging components) within the meaning of the term "food." Manifestly, this was done to facilitate the enforcement provisions of the bill so as to authorize the seizure of untested additives or shipments occurring without prior notice to FDA. In the case of pesticides, FDA was denied this power, it being felt that the law should focus on food-bearing poisons, not on poisons that might get into food. If this is true in the case of pesticides, which are often toxic to humans, a fortiori, it should be true in the case of additives and, even more so, the case of packaging components, which would never approach the toxic propensities of pesticides. Inclusion of the term "chemical additive" within the meaning of the term "food" opens a Pandora's box of unimaginable consequences because it subjects packaging components to all of the food laws. Laws written in 1938 with food in mind should not be indelicately applied to packaging components without careful deliberation. We believe that appropriate amendment can be made by—

(1) Deleting section 201 (f) (4); and

(2) Rewriting the enforcement mechanism, or adding to section 201 (f) (4) the clause "Chemical additives shall be deemed to be food for the purposes of sections 402 (a) (1), 402 (a) (2), 301 (a), 301 (c), 302, and 304."

In addition, we suggest clarifying the meaning of the term "safe for use" by adding the following definition to section 201 of the act:

"(t) The term 'safe for use' when used with reference to a new food additive shall mean that it is reasonably probable that such new food additive can be used under the conditions of its intended use without rendering the food in or on which it is used injurious to health."

In conclusion, we wish to make two points:

(1) Most members of our industry are in the small-business category. Although a few companies can bear the added costs of licensing legislation, such costs seriously jeopardize the ability of small business to survive.

(2) Adoption of H. R. 6747, or a similar measure, would undoubtedly require an immense increase in the FDA budget. Manufacturers subject to FDA

jurisdiction today find that the agency's lack of funds and, in turn, lack of personnel, tends to create situations where the exploitation of new markets and commercial opportunities must await the action of an understaffed, overworked group of dedicated men. Because of their lack of facilities, they are often unable to render prompt decisions. Advancement of food-packaging technology should not be retarded by being tied to an unduly restrictive law.

Thank you, Mr. Chairman.

Mr. WILLIAMS. This morning the committee is pleased to welcome three of our distinguished colleagues in the House who have been very active in attempting to work out a solution to the food-additive problem. They are Dr. A. L. Miller, of Nebraska; Mrs. Sullivan, of Missouri; and Mr. Delaney, of New York.

Dr. Miller, I believe you are the first to be scheduled this morning, and the committee will be pleased to hear you, sir.

STATEMENT OF HON. A. L. MILLER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEBRASKA

Mr. MILLER. Thank you very much, Mr. Chairman, and I appreciate the opportunity to appear before you today on the important subject of chemical additives in food.

As you know, I am a physician and surgeon. I have long been interested in the proper protection of the public in the use of food additives. I am also a strong believer in the free-enterprise system in which we give industry a rather free hand to go forward.

I was on a special committee several years ago, with Mr. Delaney and others in Congress, and we spent a considerable amount of time and heard much testimony on all the phases of chemicals then being used in food.

This is a rapidly growing industry. Many of these additives to our food supply make it a better food, not only in appearance but in taste and desirability. It would not be possible to have such a wide variety of food or have food so carefully presented to the public through so many packaging ideas without the use of certain additives to the food.

One of the significant changes in the past two decades in the American way of life has been that of the scientific improvement in the dynamic and rapidly growing business of food technology.

Science has been dealing in research which has opened up new frontiers. This science has helped to create new industry, new and better jobs, and more and better things for a growing America.

The American standard of living has been greatly benefited because of the new things research has been able to accomplish. I believe there will also be unexplored horizons waiting for someone to unlock the mysterious door to future advancement. The field of chemistry is vast; its potentials are only now being tapped.

This committee and the Congress should not place a stumbling block in the way of future research in the business of adding additives to food which would improve our supply and quality.

Food-additive bills have been introduced in the last three sessions of Congress. In my opinion, many of the controversies in this complicated legislative procedure have now been ironed out.

I do not claim that the bill I have introduced is perfect. It does represent hours of study and conferences between industry, the Food and Drug Administration, and others interested in the food industry.

The several bills in the committee could act as helpful vehicles for good, sound legislative procedure in governing the use of chemicals and certain additives in the processing and handling of all food.

In considering these food-additive bills, one should keep in mind that the public interest is first; and, second, we should try and work out procedures which will be a guidepost for the Food and Drug Administration and industry. If this is done, it will bring this important and sensitive field into proper perspective.

I believe that industry and the Food and Drug Administration recognize that the present laws do not provide adequate safeguards to guarantee a food supply absolutely free of additives which might bring injury to public health.

I am almost certain that Congress would not permit any administrative officials to wield arbitrary and unlimited authority without technical review or court decision or grant authority of strangling any industry.

It seems also true that industry under the present law is capable, if they so desire, of bypassing the rules and regulations of the Food and Drug Administration. These things must be brought into proper perspective and corrected.

The bill I have introduced seeks to strike a balance between industry and the Food and Drug Administration, also keeping in mind the paramount interest lies in protecting the general public.

The several bills introduced on additives in food all have for their prime purpose the protection of the public. In my bill, H. R. 8112, I have tried to spell out the rights and powers of the Food and Drug Administration. I have felt, while we need a strong Food and Drug Administration, we must not permit an administrator at some future time the arbitrary power and authority that would cripple or slow up scientific experiments.

The bill attempts to set up definite instructions as to the procedure in the use of new items that might be added to the food supply.

This committee considered now Public Law 518 in the 83d Congress, which is commonly known as the Miller pesticide residue amendment. The additives in food amendment should not be confused with the pesticide bill. They are now properly regulated by the Department of Agriculture and the Food and Drug Administration.

In my opinion, Congress intended to regulate the pesticide chemicals entirely separate and apart from the so-called food-additive amendment. The pesticide chemicals are now classified and regulated. The public is protected.

Mr. Larrick, of the Food and Drug Administration, a few weeks ago indicated there were about 750 chemicals being used in food, of which perhaps 150 to 200 had not been adequately tested.

I do not know that this needs to cause a great deal of concern, because in my contact with the chemicals in food industry I am convinced that they are very careful to make sure that no chemical or additive is injected in food that might be harmful.

In fact, Mr. Chairman and members of the committee, there are times when I have been a bit concerned about the nationwide program making some people fearful that they are ingesting small doses of cancer-forming material. I believe many of these articles are dis-

torted, and tend to undermine public confidence in the food industry.

In my opinion, good legislation might well follow the pattern and provisions of the pesticide bill and require that before any chemicals are used, that industry furnish sufficient and ample scientific evidence that the additives are not harmful to human beings. These safeguards would go into effect before the additives are used, and not after.

The bill H. R. 8112 calls for a panel of experts to help decide the highly technical and difficult problems when industry and the Administration disagree. The council, of course, is advisory. There is a definite time limit to render a decision.

Either side may call upon the advisory council for their opinion. Either side to the controversy would still have an opportunity to go to the courts and present their claims. I believe that is the American way of doing the job. It would naturally follow as evidence that the conclusion reached by the scientific panel would weigh heavily in any court decision. It seems to me that this expert panel would provide sort of a safety valve to give additional protection not only to industry but to the Food and Drug Administration.

I would call the committee's attention to the language in H. R. 8112 on page 2, line 25, and on page 3, the first six lines. This deals with the so-called incidental food additives.

I believe this is important because it covers packaging and other modern methods of handling food from which some contamination might occur. It makes it possible for the Food and Drug Administration to require that these incidental food additives be tested if there is any suspicion that they are leaving a residue that might be harmful.

The "intentional additives" are dealt with beginning in section 409.

It occurs to me that pretesting of an intentional additive is a must. Under the present law, many of these additives can be used for a long period of time, and the only weapon held by the Food and Drug Administration is an injunctive procedure.

It is not enough that industry can notify the Department of their intention to use food additives. They should first be proven not to be harmful.

An example of an "incidental food additive" might well come with the use of certain milk containers or wax containers in which food might be stored. The amount of the chemicals would be so infinitesimal that it need not cause worry; but there may be times when unintentional chemicals would cause some concern. If they do, they ought to be treated as any other additive in food.

The legislation which I have proposed differs somewhat from the others in relation to the so-called additives that would come under the "grandfather clause." It is my opinion that additives which have long been used in food could continue to be used without going through an exhaustive and expensive pretesting stage.

I do feel, however, and the bill so provides, if there are certain additives under suspicion, that then proper notice should be given to industry and they would be subject to the same treatment as new additives.

I have confidence that this committee will consider carefully the several bills before them. The subject is of so much importance it must not be treated lightly. We must give the Food and Drug Ad-

ministrator the authority which he needs, and we must see that industry is not unduly hampered.

I have confidence that, if science and research are not severely hampered, we will find the horizons of tomorrow will show still further progress for the food industry. The scientists, through research, are uncovering the secrets of nature and helping us to weave a new fabric of a better life.

There is national and worldwide interest in the business of producing and protecting our food supply. This committee and the Congress should do nothing to undermine the public's confidence in the food supply. We should approach the problem with an objective mind.

Thank you, Mr. Chairman.

Mr. WILLIAMS. Thank you, Doctor, for an excellent statement.

Are there any questions of the witness?

Mr. DIES. I would like to ask the doctor a few questions.

Doctor, I think we are all agreed on the necessity for pretesting. You feel that we ought to except from any bill all those additives which have been long used and found to be safe?

Mr. MILLER. Well, I think so. Now, common salt is, we know, an additive, a chemical, and it ought to be exempted. But if there is any question about them being unsafe they should seek approval.

Mr. DIES. That is what I was coming to, right there.

Mr. MILLER. Yes.

Mr. DIES. Let us see. The Administration bill proposes to set up this standard that if it is generally recognized by experts to be safe they do not need to pretest it. They say that has worked in other bills, other laws.

I am hoping we can make it a little more definite than that, and provide for some period of time in which the Department will declare all those additives that are expected, so that the industry will know for certain which additive is excepted from it and which is not.

Then on the question, what I wanted to ask you, on the question of those additives, you feel as to those additives, provision ought to be made so that if any additive comes under suspicion, it can then be tested?

Mr. MILLER. Yes, I do; and I think the atmosphere ought to be cleared as to whether they are or are not under suspicion.

Mr. DIES. If it is under suspicion, you would have the law provide that the Administration must notify the industry that a certain additive which has heretofore been expected is now under suspicion.

Do you not think the Administration should furnish the industry with some information, some data, justifying their suspicions?

Mr. MILLER. I would think they would; yes. I think they should.

Mr. DIES. Then, having furnished the industry that, you would place the burden then upon the industry as in the first instance?

Mr. MILLER. Yes; I would.

Mr. DIES. To prove that the additive is safe.

Mr. MILLER. That is right.

Mr. DIES. Is that right?

Mr. MILLER. Yes; I would. I think many of them might come before the scientific council for a determination by such a board.

Mr. DIES. You would not have any objection to some requirement that the Administration would publish a "white list," would you; furnish it to the industry?

Mr. MILLER. I would have no objection, and I do not think industry should have any objection.

Mr. DIES. It just seems to me something like that ought to be done, because the general, vague definition of something "generally recognized by experts" may cause confusion. They say it works pretty well administratively.

That may very well be, because the present Administrator may be more competent than some may be sometime in the future. But in writing legislation, Congress has to assume that every once in a while you will get some man who is not competent or who is arbitrary.

On this functional value, there is another point of some dispute. Do you think that the Administration should have the right to determine the question of the functional value of something that is poisonous or deleterious in itself?

Mr. MILLER. Well, I think it depends on what you define as functional.

Mr. DIES. They just use the words "functional value."

Mr. MILLER. I am never quite clear in my mind what the Administrator in the past has meant by "functional value."

Whether it is the color of the food, or whether it is the way it is wrapped, or whether there is something that is placed in the food, an additive of some type, if it is an additive that is in the food, it ought to be subject to proof of its use in the food and of its safety.

On the other hand, I do not think going so far as saying we are going to color it pink or red to make it appeal to the housewife's eye, if there is no chemical additive, then that functional value, whether it is wrapped in cloth or whether it is wrapped in a pretty piece of paper, ought not to be of any particular concern to the Administrator.

Mr. DIES. Of course, under the present law, as I understand it, and I may be mistaken about this, but the Department does have a right to pass on the functional value.

Mr. MILLER. I think that is right.

Mr. DIES. In other words, under the law now, if it is poisonous or deleterious, it cannot be used.

Mr. MILLER. That is right.

Mr. DIES. But the industry says that if you let the Department pass on the functional value, then the question of free enterprise comes into play. In other words, you are actually giving the Department the right to say how you should operate your business.

Mr. MILLER. Yes.

Mr. DIES. Suppose, for instance, take the case of oranges. We had that before our committee, where the color in gross quantity is poisonous, coal tar is poisonous, but in small doses the use of coal tar in the coloring of oranges is not harmful; at least, most of the experts say it is not harmful.

Now, suppose the Department should rule and say, "Well, we don't think that is the proper function of an additive." I do not think they would say that. But the theory is, you give the Department so much power when you give the Department the right to pass on the functional value.

On the other hand, they say if you do not give them the right to pass on it, you will be permitting poisonous or deleterious additives to be used. And while, under the present scientific testing, that may not appear to be harmful, yet there is room for doubt that the cu-

mulative effect of all such poisonous and deleterious substances may in time have a harmful effect upon the human body.

So that is a rather complicated phase of this thing. What is your idea about that? How far would you go on functional value?

Mr. MILLER. I think the line of demarcation is rather sharp. If there is any chemical being used on the orange to improve its appearance which might get into the orange juice, then, of course, that gets into your additives in food.

Our special committee investigating chemicals in food, 5, 6 years ago, ran into cases of some people who were using a certain insecticide to kill mites down in the orange-raising sections, and they were selling that orange juice to a babies' hospital. Many of the infants got sick.

They found later on, in running it down, that giving the orange juice to rats killed the rats. Here was a case of an unauthorized insecticide being used to kill mites—effective, yes; but it penetrated into the orange.

And that, of course, has to be under strict supervision, as it is now in the Pesticide Act, and it should be controlled in the food.

But I think the other side of the demarcation is this: that the Department ought to have little or no interest as to who is going to wrap what in a colored piece of paper or wax paper to make it look more attractive, which is a functional development in the food industry, whether it is frozen, as long as that packaged material does not put anything into the food. There might be an incidental addition to the food which is so infinitesimal that it causes no concern. The Department ought not to be interested in that phase of the food business.

And I think in some instances they have gone so far, and can under the present law, as to say that you cannot wrap food in this or that material, or you cannot use milk containers of certain pasteboard, or you cannot use certain things to make food look a little better. And that is the demarcation between incidental and nonincidental additives. But if there is anything that gets into that food in the process of making the functional design, then it ought to be subject to the provisions of the additive bill.

Mr. DIES. Then we will have to devise some definition of "functional value" which will clearly separate that.

Mr. MILLER. Yes.

Mr. DIES. The general words—the general phrase "functional value" would give tremendous power to the Department, would it not?

Mr. MILLER. You are right; yes.

Mr. DIES. Let me ask you—the reason I am asking you these questions is because you are a student of it and you had the advantage of serving on this special investigating committee, and you and Mr. Delaney and others who did got a great deal of information which this committee has not had an opportunity to get.

There is another bone of contention in this whole matter, and it was in 1956 and it will be this year. That is the matter of after you pretest and the Department says, "Our opinion is that this should not be used," and the industry says, "Well, we think it should be used."

Now, under the bills which have been proposed, the Department has a right to enjoin the use of it, get out a temporary injunction and immediately restrain it, and then you go into the question of trial.

Last year there were a great many who believed that it ought to be in the district court. Well, I did not agree with that, because you certainly could not have a trial; the Federal courts are already cluttered up—they can hardly find time to try their cases.

Down in my country I know it is a very serious situation; and if you went into the Federal courts on every one of these cases, you would never have any administration—at least, that is what I fear about the matter.

What is your view about that?

Mr. MILLER. I would agree with the gentleman on that provision. I am not a lawyer, as you know, and you know far more about the court procedure than I would. That is one reason that in this bill, as we provided in the pesticide bill, we have sort of a safety valve, either to the industry or Department.

If the Department says, "This chemical should not be used," and industry says, "We think it should be used," I think they should be able to go to some court. But first they ought to go to the advisory council, made up of National Research Council men, scientific men who can make a decision. We did that in the pesticide bill, and I think it is working well.

Mr. DIES. Should not some prima facie, what we call in the law a prima facie presumption, be attached to the experts' opinion?

What troubles me is the fact that a court, passing upon highly technical matters, especially if you have a jury trial, which you would be entitled to under some circumstances, that they would find it very difficult to decide who was right about it. I mean, this is a technical question, purely technical, and the average layman finds the greatest difficulty understanding it.

On the other hand, the present Administrative Procedure Act has many objections, is under serious consideration for revision, because actually it is meaningless under the interpretation of the substantial evidence rule. As it has been interpreted, the finding of the Administrator is, for all intents and purposes, really conclusive.

I think every lawyer who has had occasion to appeal cases from administrative rulings will agree that it is very rare that the courts can do anything about it. If there is any evidence at all to support the Government, the courts say, "Well, there is nothing we can do about it."

So some appeal method must be worked out in this bill, if possible, which will meet that situation.

Do you have any suggestion to make along that line?

Mr. MILLER. Yes. We provide in the bill, of course, a public hearing should always be held. Then the expert panel, made up of men of scientific knowledge, come into the picture.

Mr. DIES. They pass on it after the ruling by the Administrator?

Mr. MILLER. That is right; they may either before or after the ruling by the Administrator.

And then, if either side is not satisfied, let them go to some court, and I do not know whether it should be the district court or a Federal court or some other court. But the court should then have the right to take under consideration the decision and findings of the scientific council, which, under the pesticide bill, has worked in 1 or 2 cases very well.

The individual going to court would certainly have two strikes on him, as we would say in baseball, if they would take into consideration the decision made by the expert panel, and they should do it, and then we provide also, in disagreements of this kind, that it not drag out for years, as was done in the bread hearings, which went on for 2 or 3 years. I do not know whether it is settled yet.

We provide a 90-day finding by the Administrator, and it gives industry a right to know whether they are right or wrong in using a certain chemical or chemical additive they propose to use.

But I think the bill I have introduced, and some of the other bills have the proceedings of the public hearings, the use of the expert council, and then, of course, the right to go to court.

I think we would be wrong in denying either industry or the Administrator the right to go finally to court, if it is a problem of enough importance.

Mr. DIES. That is all, Mr. Chairman.

Mr. WILLIAMS. Mr. Bush?

Mr. BUSH. Mr. Chairman, I want to apologize for being detained. It made it impossible for me to get here earlier.

Doctor, do you feel that any of these additives, chemical additives, in our foods today are injurious to the health of our people?

Mr. MILLER. I said in my statement——

Mr. BUSH. I mean which are being used today.

Mr. MILLER. I said in my statement, Mr. Larrick, the Administrator of Food and Drugs, said there were some 750 being used, and probably 150 to 200 that had not been adequately tested. That was in the U. S. News recently.

I do not think, as stated in some of the articles coming to my desk now, that it is true people are ingesting a little bit of cancer every day. I got such a letter this morning.

I feel it is these sensational articles that have a tendency to undermine the confidence of the public in the great chemical industry. I think the proper use of chemical additives in food has greatly improved our food supply and made it possible to have a more abundant food supply and more attractively packaged and a better quality than we would have if we were not using some of these important additives in food.

It is a tremendous stride we have made, most of it in the last 10 years, and in the next 10 years we are going to see far more than we have seen in the past in the use of uranium byproducts and isotopes in preserving and preparing and keeping food, and I think we ought to do everything we can to encourage scientific research along those lines.

Mr. BUSH. I agree with that statement.

Do you think we have had experience enough to show cumulative effects on human beings with some of these additives?

Mr. MILLER. Well, that is a very debatable question. I think on many additives that have been used over a long period of time, yes. There is some question as to whether certain chemicals being used might have a bad effect upon the human system.

I am thinking now of some of the coal-tar end products, cigarette smoking, that I believe this committee or some committee is shortly going to investigate to try to discover whether filters are taking out

the poison. But that is a wide-open, debatable question, I think, among excellent scientists.

But let me say this: I feel industry and the Food and Drug Administration have been most careful and on the job in trying to protect the American food supply. They have done a good job.

Of course, in a tough economic world, there is always someone who is going to cut corners. That is the reason we need a law, a change in the law, so that we can protect the public from someone who might want to cut some economic corners and use something which might not have had the approval of good scientific men.

Mr. BUSH. Thank you, Doctor. That is all.

Mr. WILLIAMS. Mr. Rhodes?

Mr. RHODES. I have no questions.

Mr. WILLIAMS. Mr. Heselton?

Mr. O'Brien?

Mr. O'BRIEN. No questions.

Mr. WILLIAMS. Mr. Schenck?

Mr. SCHENCK. Thank you, Mr. Chairman.

I have been very deeply interested in Dr. Miller's statement, because I think he is well qualified to discuss these questions.

Some several years ago, a subcommittee of this committee had some hearings on pesticides and insecticides, and there was considerable testimony regarding residuals of spray, such as DDT, and other residuals which are used by orchardists and by growers and farmers and gardeners, and so on.

I was very much interested in your colloquy with our distinguished friend and colleague from Texas, Mr. Dies, on the coloring of oranges.

We all know that, in groceries throughout the country, orange-juice machines squeeze the whole orange, and certainly some of these residuals get into the juice. Would you think that might be harmful?

Mr. MILLER. If there is any question about them getting in, then they ought to be subject to the same approval as any other additive in food.

Mr. SCHENCK. It has been my observation that they take the oranges out of the crates, put them in machines, and squeeze them, the whole orange, and I am just wondering if there is not the possibility of some harmful results.

Mr. MILLER. Undoubtedly, some of those insecticides, pesticides, rodenticides, get into the food supply.

But if people follow the directions in the use of different pesticides in the development of food, the amount is small, very small, and I think not harmful to the food supply, and that is protected now by the Agriculture Department and the Food and Drug Administration.

Mr. SCHENCK. Well, as I recall the testimony in this hearing several years ago, the residual of these sprays and treatments is not soluble, and therefore cannot be washed off by the housewife or anyone else processing the fruit.

Is there substantial evidence on that?

Mr. MILLER. In the use of sprays and insecticides, under the directions that are set up, you are not supposed to use them a certain number of days before you pick them and send them to market; and under the Pesticides Act, if they find people using improper sprays, not

using them properly, and they find too large a residue on that apple or orange, then there is power, under that act, to condemn and hold those oranges and apples or food or lettuce, or whatever it is, off the market.

Mr. SCHENCK. Well now, is not the medical profession and the general scientific community constantly developing new information as a result of their constant study on these questions?

Mr. MILLER. Oh, yes, indeed, Mr. Schenck.

I addressed a group of pharmacists not too far back, and the president of the national organization said that 75 percent of the prescriptions written in Washington, D. C., today were not known 15 years ago, and that is how fast the drug end of it has grown. The additives to food business has had a tremendous growth.

Mr. SCHENCK. And, therefore, some of the food additives which have been used over a long period of time, which have been considered as not being harmful, might be discovered to be harmful?

Mr. MILLER. I think some of them that are presently being used, Mr. Larrick says 150 or 200 of them have not been properly tested, and certainly ought to be examined very carefully, as should the new ones that are coming in every day in the use in food.

Mr. SCHENCK. Then may we take it that it is your position that all of these food additives, even those which have been used a long time, and those that have not been pretested, ought to be continuously tested in the light of new scientific developments?

Mr. MILLER. Well, I feel there is a whole group of chemicals in food, and common salt is one of them, that need not go through the exhaustive, expensive process of examination to find out whether it is harmful or not.

If there is any question from the Food and Drug Administration that some of these presently 150 or so might be harmful, then they ought to go through all of the pretesting data required.

At the present time, a manufacturer may decide to use a chemical. He notifies the Food and Drug Administration, and then goes ahead and uses it, and it is used right along, unless the Food and Drug Administration steps in and says, "Wait a minute. You can't use that," and gets an injunction to stop them.

And it is a costly, time-consuming process, as it was in the bread hearings. They went on and on and on, and yet all the time it was being used in our food supply.

I think the bills before you prevent just that thing happening, and that is one of the big things this committee can do to prevent maybe a few of the unscrupulous—and there are only a few in the tough economic world—that would do that. But it has been done in the past. And the public needs the protection.

Mr. SCHENCK. Well, Dr. Miller, is it not true that there are many illnesses and diseases——

Mr. MILLER. Many what?

Mr. SCHENCK. Is it not true there are many illnesses and diseases at the present time, the cause for which has not been definitely determined?

Mr. MILLER. Well, that is true, yes; a few of them.

Mr. SCHENCK. Many of these occur in the field of general allergy.

Mr. MILLER. Well, I would say there were some. I think, Mr. Schenck, you and I live, of course, in a world where men, honest and

sincere men, may, can, and do differ in their opinions. I think you will have a witness today or tomorrow who will tell you that many of the diseases affecting the human race are caused by the food we eat.

I am not one who believes that, and I think the best scientific minds would disagree with that position. But you will find a few scientists who will tell you that most of our problems come from eating chemicals.

The organic people are now in the field with a great "Don't ever use pesticides or chemicals of any kind to produce food. If you do, you will get a little cancer."

And I have gotten literature on my desk a foot high which indicates that there is a lot of propaganda going out, and I think it does immense harm to good, honest, sincere administrators in Food and Drug, and people in the chemical industry and the food industry, as to what happens in the food supply.

It is an emotional problem which can be developed to an extent that I think you and I, as constructive, objective individuals, must weigh very carefully in our decisions on legislation.

Mr. SCHENCK. I have only one more question.

Of course, it is well known that I am neither a doctor nor a lawyer—and I may not pronounce this correctly—but I understand that there is an illness called lupus erythematosus which, although it has been studied for many, many years, the cause is not yet known, and it can often be a very serious result if it gets into the bloodstream, somewhat similar to leukemia, although it is supposed to not be malignant.

It is my understanding that many of the medical men who have been making studies on that matter for many years are now about to conclude that it is in the general field of allergy, and that many of these food additives, many of the residual sprays, and so forth, can easily promote and develop such a disease, which is extremely dangerous and extremely unpleasant.

That is one of the reasons—I know a little about that, and that is one of the reasons why I am very much concerned about this, and it would seem, therefore, to me that even though additives, pesticides, insecticides, and residuals, in their accumulation may have come to be accepted, that there is still much to be done, and that in the future any developments resulting from scientific studies must have proper consideration.

Mr. MILLER. That might be true, Mr. Schenck.

There are many blood dyscrasias and other diseases of the human being that still are somewhat of a mystery, but they are certainly becoming fewer and fewer every year as science digs in deeper and deeper, finding the cause and cure of all these diseases.

And that is true of these additives in food. I think scientific men have to be constantly on guard in research and otherwise, trying to discover if there is any ill effect. And, of course, if there is any ill effect, I think somebody in the Administration must have the authority to step in and stop its use.

But so far, I think scientific research—and that is the thing I hope we never in any manner hobble or shackle, that they be permitted to go forward to make the full, complete research as to whether there is any harmwul effect from any additive or pesticide that might be used in our food supply.

Mr. SCHENCK. Thank you very much.

Mr. BUSH. Will the gentleman yield?

Mr. SCHENCK. Yes.

Mr. BUSH. Doctor, before we started to use these chemical additives in our food, is it not a pretty well known fact we had these diseases at that time?

Mr. MILLER. Well, they were recognized, some of them, but we did not know what they were.

Mr. BUSH. But we had them?

Mr. MILLER. We had them.

Mr. BUSH. That is all.

Mr. WILLIAMS. Thank you.

Mr. SCHENCK. Thank you, Mr. Chairman.

Mr. WILLIAMS. Mr. Dingell?

Mr. DINGELL. No questions.

Mr. WILLIAMS. Dr. Neal?

Mr. NEAL. Dr. Miller, as a practitioner of medicine for a great many years before you came to Congress, and in view of the fact that during all these years you have had the opportunity to get into the study of the deleterious effects of additives and things of that nature, I certainly feel that your general approach to the whole medical and scientific field is much broader than that of the average man who has only practiced medicine for a few years.

But in view of the fact that, we will say, in your experience as a physician, I do not know whether you can go back as far as I have, but it has been my experience that throughout the whole medical history many drugs, many remedies, many so-called positive cures have come onto the scene from time to time, and occupied the stage and were accepted generally by both medical people and the patients, and within just a few years that particular thing which was so well accepted has passed out of the picture and no longer is being considered.

Well, from time to time during the whole process and advancement of the medical profession, along with the other associated sciences, during all these years, we come to the question right now of the general progress that is apt to be pursued or apt to come about by reason of continuous study of such things as additives for the prevention of disease or additives for the preservation of food or for the processing in such manner that it makes it appear to the eye a little bit more tasty, and all that.

This extensive investigation, chemical discoveries, going on from time to time, is bound to result in new things from time to time. The main thing I want to bring out is that whatever we have in the way of additives today that may be, by reason of their experience over a number of years, accepted as harmless, we go along, and in this particular legislation we try to make provisions where we will not question the results of these additives, but we will take the position that new additives must be tried out and experimented with and thoroughly examined before we permit them to be used in foods. And I think that is a very good thing.

But the main thing is this: That in view of the fact that we know, generally speaking, all industrial people are just like anybody else who deals with the public, primarily interested in doing the very best they can under the circumstances, and that the great majority of the industrialists and the food processors and even the growers of food

who use pesticides are going to be on the alert, and, of course, in every way possible they will avoid anything that would reflect itself in the disease of the communities, but there are always a few, as you said a while ago, who take advantage of an opportunity; and my thought is, in regard to this bill, that a good bit of authority should be given to the Food and Drug people to enable them to be in position to determine from time to time all new additives that come along in such a way that they should be the things that have the least prospect of having any harmful effect on humankind.

Mr. MILLER. I agree with you, Dr. Neal, and may I add this: That I am convinced if we had not had the use of pesticides now, that are approved by the Agriculture Department and the Food and Drug Administration, we would not be able to produce and have before the American people the vast supply of fresh vegetables and fruits that we are now using, selected pesticides, to combat the insect world. And there are new insects all the time. They require new pesticides to control them.

The same is true of certain additives to food: We would not have such a good food supply without the use of such additives.

Mr. NEAL. I recognize that to be quite a truism.

Now, we look upon life as having been very greatly extended, the average life, in the past 50 years, or at least approximately that period.

Would you not believe that the ability of the producers of food and the manner in which foods have been handled and displayed, the opportunity for the average individual to secure a variety of foods in this day under present situations, under present existing conditions of producing and transporting food, has enabled, perhaps been more influential in the process that has extended life than anything else?

All year around now, people have access to a very great variety of foods, and they can satisfy their own appetites, and they can indulge in a variety which gives them a certain amount of protection against disease that people who formerly were deprived of the opportunity, at certain seasons of the year, of getting the type of thing that they probably craved, were most susceptible to disease.

I wonder if you think this has been a very effective cause of the extension of life?

Mr. MILLER. I am sure, Doctor, it has been one of the factors that has added length to human life, as well as progress made by medical science, wrestling with diseases of various kinds and conquering them.

And, of course, our food supply has been most important in keeping up a strong healthy body. We are the best fed, best clothed people in all the world, and we have a longer life span than we had 50 or a hundred years ago.

It is constantly increasing, and I think due to medical science, food science, and it has been a big factor, and I feel it will increase as we develop new scientific factors that add to those longevity factors.

Mr. NEAL. Thank you, Doctor.

That is all.

Mr. WILLIAMS. Mr. Loser?

Mr. LOSER. Nothing at all, Mr. Chairman.

Mr. WILLIAMS. Mr. Dollinger, would you like to question the witness?

Mr. DOLLINGER. No, Mr. Chairman.

Mr. WILLIAMS. Dr. Miller, I believe all the questions I had in mind have been answered with the exception of 1 or 2 matters that perhaps might have been clarified by you with respect to the difference between your bill and some of the other bills that are presently before the committee.

Your bill, if I am not mistaken, is the only bill which makes reference to incidental additives.

Mr. MILLER. Yes.

Mr. WILLIAMS. And, to a certain extent, it treats incidental additives in the same manner as it would intentional additives.

Mr. MILLER. Right.

Mr. WILLIAMS. Except that I notice that your bill sets up or would provide for an advisory committee with respect to intentional additives, but would not with respect to incidental additives.

Mr. MILLER. Well, if the incidental additives are under suspicion, yes; the advisory committee would act in the same capacity.

Mr. WILLIAMS. Then the advisory committee would be empowered or authorized to give study to the incidental additives?

Mr. MILLER. I would want it that way; yes.

Mr. WILLIAMS. I notice that your bill would provide for a public hearing with respect to intentional additives, but there is no provision for a public hearing with respect to incidental food additives. Is there a reason?

Mr. MILLER. I think there should be a public hearing if they are under suspicion. I left it out because most of the incidental additives will never come up for a contest. They will say they are all right.

But if they should come up, if this cup here, the stuff that is used in the lining of this cup, ever comes up and they say too much of whatever it is gets into the water you drink, then it ought to be subject to the same thing as an intentional additive; exactly the same.

Mr. WILLIAMS. What procedure is provided in your bill with respect to judicial review of the action of the Food and Drug Administration?

Mr. MILLER. Well, you have a court procedure, you have a public hearing, of course, and a hearing in a court. I am not particular as to what court. I am not a lawyer, and I do not know where they should go. But I think before they do that you ought to have the advisory board in between the dispute and the court, so the court would have somebody to sort of give them expert advice, because these problems are so technical that the ordinary court or jury would not understand them.

Mr. WILLIAMS. Doctor, thank you very much for very enlightening testimony. I think everyone will agree that you are thoroughly familiar with your subject, and we are very pleased to have you this morning, and we thank you.

Mr. MILLER. Thank you. You have been most kind.

Mr. WILLIAMS. I believe the next witness scheduled this morning is Congresswoman Sullivan.

Mrs. Sullivan, we are very pleased to have you before this committee, and we will be glad to receive your testimony.

STATEMENT OF HON. LEONOR K. SULLIVAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mrs. SULLIVAN. Thank you, Mr. Chairman.

If it is acceptable to the committee, I would like to read my very short statement and turn any technical questions over to the scientists. I understand you have some experts here this morning, brought in by Mr. Delaney, to answer some of the many questions that you gentlemen have in mind. I think they could give you a lot more valuable information, probably, than I could.

Mr. Chairman, I am the sponsor of two of the bills now before the committee to curb the use of unproved or unsafe chemical additives in foods and cosmetics. My bills are H. R. 4431, dealing with cosmetics, and H. R. 7939, dealing with foodstuffs.

While I have introduced these bills—and thoroughly and completely believe in their purpose—it is only fair to say that what I have done is to take the two bills introduced by Congressman James J. Delaney, of New York, the man who has been leading this fight in the Congress for many years, and I have, in effect, cosponsored his bills.

Mr. WILLIAMS. Your bill is identical with his bill?

Mrs. SULLIVAN. Yes; it is.

Congressman Delaney, as a result of the intensive study he has made of this subject as chairman of a special committee of the Congress several years ago, is an expert on every phase of this matter.

I have to acknowledge that I am not an expert in the technical aspects of the legislation—the legal provisions which seem to have been so controversial in the past.

But I do feel qualified to discuss with you tthe need of the American consumer and the American family for greater assurance than now exists that the foods we buy, the prepared foods, and the cosmetics we buy, do not have lurking in them ingredients which are going to kill us from cancer or inflict upon us other diseases of one sort or another.

Presumably this was a battle which was won for the American consumer 51 years ago in 1906, when Congress enacted the original Food and Drug Act. Presumably any loopholes in the act were tightened in the consumer interest in 1938 in the passage of the Food, Drug, and Cosmetic Act.

But, as Congressman Delaney's special committee disclosed in its comprehensive investigation, and as officials of the Food and Drug Administration acknowledge, there are chemical additives being used in food and in cosmetics which we do not know for sure will kill any of us from cancer when used in the manner authorized by the Food and Drug Administration, but which we do not know for sure will not lead to cancer or other serious illness.

Why? Because there is no law which requires that all of these chemicals be fully tested and found safe for the consumer before actually being put on the market. The law as now written does not prevent completely the use of dangerous or potentially dangerous chemical additives; rather, it just punishes the manufacturer for using it if such a chemical should later be proved to be harmful.

We do not do that with drugs. They must be proved safe before being used. Yet the chances of poisoning ourselves through the use

of an untested drug ingredient would be much less likely than through the use of untested chemicals in foods or in lipsticks or face creams or other cosmetics. Most of us buy medicines only when we are sick; usually, however, we eat 3 meals a day and, if we are of the feminine sex, beginning somewhere around the age of 5 or 6 years old, and certainly by junior high school age, these days, we are using a good many cosmetic items.

So this is a really serious problem. According to a discussion of this matter by an Assistant Secretary of Health, Education, and Welfare, Mr. Bradshaw Mintener, in a talk before the American Chemical Society last year, it is estimated that about 25,000 new chemical substances have been screened by industry's research laboratories since 1940 for possible utilization as food additives.

He said about 400 chemical substances are today actually being used for various purposes in food production, conservatively speaking. He said there actually may be about 500 of them.

Of these, about 150 are considered harmless; another 100 are safe or considered so in the quantities in which they are normally used. But here is what this official had to say about 150 remaining chemical additives now in use, and I quote Mr. Mintener:

> The remaining 150 are in a scientific "no-man's land"— they are in use but have not been adequately tested. The FDA scientists do not know whether they are safe or not, but they suspect that some of them ought not to be in use.

Thus, although we can't, as I understand it, point to a particular chemical now in use in foodstuffs and say definitely that it specifically causes cancer or other serious illness in the quantities or in the way it is used, nevertheless we cannot, either, point to it and say it does not constitute a hazard.

Now we all know that the Food and Drug Administration tries manfully to do a thorough job in testing foodstuffs and cosmetics and in going after those known to be dangerous. But it is so limited in resources—a tragic fact but a true one—that it cannot begin to test as widely as it should. Yet the burden of proof under present law is on the FDA.

It should be placed on those manufacturers who, for one reason or another, want to use these chemicals. Seldom do the chemicals add anything of nutritional value. Mostly, they are intended to cut costs, or to cut corners, or to cut spoilage or waste. They are put into the foods mostly for the manufacturer's benefit, in most cases, rather than the consumer's. Why, then, shouldn't the manufacturer shoulder the burden of proof to prove them safe?

The law should require adequate pretesting, and it should be airtight, without loopholes. I do not care how many arguments the lawyers might get into over the legal technicalities of such a law, but I say that when it comes to setting limits, when it comes to determining standards to safeguard the public, the consumer, then the scientists and doctors should have the final say, not the lawyers or judges.

This subject has received new emphasis and attention as a result of the conference in Rome last year of cancer experts who reported many chemicals are now in use which might cause cancer.

Long before that conference, however, the leaders of the consumer movement in St. Louis—and I might say we have an outstanding

consumer federation composed of dedicated women who keep a sharp eye for the consumer interest in all matters—but long before the Rome conference, these St. Louis consumer spokesmen were warning our community of the danger, and providing me with much useful information on this subject.

They feel—and I agree—that our Government must be empowered to step into this situation and really protect the consumer. That is why I support and cosponsor Congressman Delaney's bills, knowing that, based on his knowledge and experience in this field, the legislation he has drafted will in fact protect the public interest and make the public interest uppermost.

I urge you to approve the Delaney-Sullivan bills.

I thank you.

Mr. DIES. Thank you very much, Mrs. Sullivan, for your fine statement.

Any questions by any gentlemen of the committee?

Mrs. SULLIVAN. Thank you.

Mr. SCHENCK. I certainly congratulate Mrs. Sullivan for the very fine statement she has presented.

Mrs. SULLIVAN. Thank you.

Mr. BUSH. I want to join in congratulating Mrs. Sullivan. I know how interested she has been.

Mr. DIES. Congressman Delaney, I believe you have some experts that you want to introduce.

Mr. DELANEY. That is right.

Mr. DIES. Do you want to put them around the table there?

Mr. DELANEY. No. If it is the wish of the committee, I would like to make a very short statement, just a very short statement, and then I will be glad to put them on.

Mr. DIES. Thank you, Mr. Delaney. We are very glad to hear from you, because we know you have done a wonderful job in the whole field, and the expert investigation that your committee made is largely responsible for the interest in this very important matter.

Mr. DELANEY. Thank you.

Mr. DIES. You may proceed.

STATEMENT OF HON. JAMES J. DELANEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. DELANEY. Mr. Chairman and members of the committee, I appreciate the privilege of this additional appearance.

My statement will be very brief, but first I think I should deny the statement of Mrs. Sullivan that I am an expert in this field.

Mr. LOSER. I do not believe she accused you of being an expert.

Mr. DELANEY. I believe she said something to that effect. [Laughter.]

When I testified before you in March in support of H. R. 4014, I brought to your attention the views of a number of cancer researchers who are convinced that any food-additive legislation should contain a specific provision prohibiting the use of any cancer-inducing substance in food.

As a result of further study of this problem, I decided to draw up a fresh bill containing such a provision. Accordingly, on May 28, I introduced H. R. 7798, which is identical with H. R. 4014, except

for three additions: On page 3, line 18, after "chronic toxicity", I have added the word, "carcinogenicity", and on page 5, beginning on line 19, I have added:

> The Secretary shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals.

Since three noted cancer authorities are scheduled to testify as soon as I have finished, I would prefer not to take up the valuable time of the committee by commenting on these provisions on this occasion. I am sure that the views of the experts will be much more helpful to you than my views as a layman.

In addition to the ban on carcinogens, I have included two provisions recommended by the Food and Drug Administration at the chemical-additive hearings last year—one, relating to the safety of food affected by radiation, and the other, relating to chemicals used in animal foods. The first of these will be found on page 1, line 9, and page 2, line 3, and the second, beginning on line 12, page 5.

I expect that FDA representatives will discuss similar provisions in H. R. 6747 when they appear here this or next week, so in order to avoid duplication, I should like to reserve further comment at this time.

Mr. Chairman, there are present this morning three of the country's outstanding cancer researchers: Dr. William E. Smith, Dr. Francis E. Ray, and Dr. W. C. Hueper. Dr. Smith has interrupted his vacation in Maine, and Dr. Ray his vacation in Tennessee, to be here, and both have come at their own expense. I am sure that what these three eminent doctors have to say will be of great interest to you, and I not only appreciate their public spirit in being willing to give you the benefit of their experience, but I also appreciate the committee's courtesy in hearing them at this time.

I will subject myself to any questions at some future date, because, since these men have given of their time and have come at their own expense to Washington, I want you to have the benefit of their expert experience and an opportunity to cross-examine them. In their own field they are considered experts, and I prefer that you call Dr. Smith as the first witness.

Mr. DIES. Yes.

Mr. DELANEY. And he will qualify himself, and then you can ask him any questions you desire.

Dr. Smith. This is Dr. William E. Smith.

STATEMENT OF DR. WILLIAM E. SMITH, ENGLEWOOD, N. J.

Dr. SMITH. My name is William E. Smith. I live in Englewood, N. J.

I received the degree of doctor of medicine from the Johns Hopkins University in 1938. Since that time, I have engaged continuously in medical research as a full-time member of the staff of the Harvard Medical School, the Rockefeller Institute for Medical Research, the Sloan-Kettering Institute for Cancer Research, and until last year as associate professor of industrial medicine at New York University. There, I was engaged in the testing of chemicals for ability to induce cancer.

I now hold a fellowship from the American Academy of Nutrition, awarded me for study of nutrition in relation to cancer, with special

reference to chemical food additives, and pesticide residues in food.

I am appearing as a private individual and not as a representative of any organization or institution.

I have studied bills proposed to assure safety of chemicals in food, and I find that H. R. 7798, a bill introduced by Mr. Delaney, is the only bill specifying that the Secretary of Health, Education, and Welfare shall not approve for use in food any chemical additive found to induce cancer in man or, after tests, found to induce cancer in animals.

I will attempt to show that other bills will tacitly permit use of cancer-inciting chemicals, carcinogens in food. For this and other reasons, I believe that H. R. 7798 affords better protection to consumers than would be afforded by other bills.

Since the Secretary must evaluate the evidence in order to make a finding as to the cancer-inciting properties, the carcinogenicity of any chemical, I submit that the wording of the sentence, excluding carcinogens, in H. R. 7798, enables the Secretary to exercise judgment in evaluating claims for carcinogenicity of chemicals.

This should avoid possible hardships from occasional reports of cancer induced by unusual procedures, such as injuries produced by subcutaneous injections of concentrated solutions of common sugar or repeated surface applications of some common acids.

The fact that some chemicals can induce cancer in human beings has been well established. An important and pecular characteristic of these chemicals is that they exert their effects only after long periods of time. In human beings, chemical-induced cancers may not appear until 20, 30, or even more years after the first exposure.

To determine the ability of a new chemical to induce cancer in human beings would thus require a generation of observation. For this reason, animals that have shorter life spans are commonly used to test chemicals for possible cancer hazards. Several hundred chemicals have already been found to have the property of inducing cancer in animals.

Some of these induce cancer in certain species but not in others. For this reason, when a chemical is found to induce cancer in animals, one cannot be certain that it will also induce cancer in human beings. If such a chemical is widely distributed in food, however, consumers would have to accept needless risks that could spell irreparable harm. Carcinogens have the unusual property of inducing irreversible changes in living cells, so that the cells slowly progress to cancer long after treatment with the chemical is stopped.

For this reason, a carcinogen introduced into the Nation's food supply tomorrow could, even though subsequently reconsidered and withdrawn, induce cancer many years later in individuals who consumed it.

A publication issued last December by the Food Protection Committee of the National Research Council contained the following statement, and I quote:

> The conservative position would demand that substances that produce cancer in experimental animals should be excluded from human foods as a precautionary measure, even though it is known that a substance carcinogenic in one species is not necessarily carcinogenic in others.

Now, during the past 7 years, my work at New York University was primarily with chemical companies for the purpose of testing

chemicals upon animals for ability to induce cancer. The object of these tests was to detect any hazards for workers or consumers. In the course of this work, I induced cancer with a variety of substances in several thousand animals.

Companies with which I have worked—and these include some of the largest corporations in the country—have made extensive arrangements to protect human beings against exposure to materials that were found to induce cancer in animals.

In 1954, and again in 1956, committees of the International Union Against Cancer adopted resolutions calling for the testing of chemical food additives for carcinogenicity upon animals, and exclusion for use in food of any amount of any chemical found to induce cancer.

These resolutions endorsed the view that safe doses cannot be established with confidence for carcinogens because of their unusual pharmacological action.

Many scientists have induced cancer late in the life of animals by giving them, when young, a single dose that could be put on the head of a pin.

Everyone accepts the fact that a few bacteria can enter the body, multiply, and cause disease. We are concerned now with the fact that a few chemical molecules can enter the body, stimulate a body cell to multiply, and as that cell and its descendants go on multiplying we eventually get a mass of cells that we call cancer.

All of the present bills to amend the food law will permit use in food of safe quantities of chemicals found harmful in higher concentration.

H. R. 7798, however, precludes extension of this safe quantity principle to carcinogens. It is the only bill that does so.

The matter has practical importance because of a recent test case, known as the Aramite decision, the details of which I offered in a letter to Mr. Delaney, published by him in the Congressional Record on February 21.

Briefly, this decision involved a pesticide chemical which the Food and Drug Administration found to induce cancer when eaten by animals. FDA's division of pharmacology stated it could not recommend that such a substance be used on food. The manufacturer requested a review. A committee met and decided that it might be safe to use a little rather than a lot. The Food and Drug Administration thereupon issued an order permitting sale of food containing small amounts of this chemical.

Now, nobody knows whether this compound or some particular dose of it will or will not cause cancer in human beings, but citizens of the country are being obliged to eat it without their consent.

The precedent of this Aramite decision opens the door for approval for use in food of so-called safe quantities of other chemicals that are found to induce cancer.

When someone has spent money developing a new chemical that he wants to sell for use in food, it is understandable that he would be reluctant to lose his investment, when animal tests disclose that his compound induces cancer.

The Aramite decision provides a convenient device for the developer of a carcinogenic food additive to go ahead and sell his product, but it leaves consumers to take the risk.

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There is, it seems to me, no moral justification for obliging consumers, many of whom are children, with life expectancies serving the long latent period of carcinogens, to accept such needless risks. Most of us are dependent upon processed food for life. We do not have the opportunity to exercise choice, as we do have in the case of exposure to carcinogens in smoking.

The Food and Drug Administration has been well aware of this problem and of the resolutions adopted by committees of the International Union Against Cancer opposing approval for use in food of carcinogens in any dose.

Last March, however, FDA came out in support of a bill, H. R. 6747, now introduced in the Senate as well, as S. 1895, which fails to contain any exclusion of carcinogens or any requirement for testing food additives for carcinogenicity. This failure is not accidental. During the past 3 years I have corresponded with the FDA about the need for such provisions. I am told that FDA prepared that bill with the knowledge and approval of food industries, but without consulting the chairman of the congressional committee that investigated the use of chemicals in food.

Now, I have genuine respect, and I mean that, for all officers of the Food and Drug Administration, and of food industries that it has been my privilege to meet. I do not know of anybody who wants to put into food any chemical that he really regards as dangerous. I believe that American industries are the finest and most public spirited in the world. When we come to the problem of carcinogens, however, their difficult evaluation and long-delayed action tends to make us adopt the attitude of a hopeful ostrich. This problem is having its growing pains.

In 1950, the National Cancer Institute of the United States Public Health Service established a program for study of environmental chemical factors in cancer. Within a few years, a Dr. A. J. Lanza, then director of the Institute of Industrial Medicine at New York University, told me that he had been retained by a group of chemical industries to call upon the Surgeon General and object to studies conducted under this program. He stated that his objections had been successful, and that all field studies by the National Cancer Institute in this program would be stopped. They were.

A few years later, I showed this same gentleman data indicating a cancer hazard for men employed in another industry that had retained him as a consultant. He advised me to keep out of this problem, and shortly thereafter notified me that my appointment as associate professor of industrial medicine at New York University would not be renewed. It was not renewed.

Last year an official of one of the large chemical companies told me that they fired their medical director because he was too interested in carcinogens in their products.

Now, this experience is not unique. Government, university, and industrial research in this field has been obstructed, while apologists for carcinogens are in great demand.

This committee of the Congress has the opportunity to act for conservative prudence in this matter through reporting out H. R. 7798, a bill drafted by the chairman of the congressional committee that investigated the use of chemicals in food, and the only bill that

offers consumers specific protection against the needless risks of cancer-inciting compounds in food.

I thank you for the opportunity that I have had to come here.

Mr. WILLIAMS. Does that conclude your statement?

Dr. SMITH. Yes, sir.

I would like to submit a written statement for the record, if I may.

Mr. WILLIAMS. If there is no objection, it will be accepted, of course, by the committee as part of your testimony.

Dr. SMITH. Thank you, sir.

(Dr. Smith did not submit a further statement.)

Mr. WILLIAMS. There may be questions on the part of the committee. I recognize Mr. Rhodes.

Mr. RHODES. I have no questions.

Mr. WILLIAMS. Mr. Bush?

Mr. BUSH. Doctor, you said in making your tests you found out that some of these short-lived animals were not subject to cancer, and others were. How do you account for that?

Dr. SMITH. We do not know very much about differences that underlie differences in response of various species. It is one of the major problems in this field.

One of the most active cancer-inciting chemicals for human beings, betanaphthylamine, fails to induce tumors in many animals, and it was not for many years that a species was found that responded in the way that men did and developed tumors after being treated with that substance.

Now, this is a phase of the problem that I think is very important for us to think about in all of this, sir, because it makes us realize that we can predict the long-term biological effects of new chemicals upon human beings only imperfectly from tests upon animals, and I submit that the adulteration of food with new chemicals is not a right, but a privilege that should be permitted only when there is real need.

H. R. 7798 specifies, as other bills do not, that chemicals should be shown to be useful to consumers, if they are going to be approved for use in food.

Mr. BUSH. Well, mostly, chemical additives that are used are used for the purposes of preservation of the particular food until it is consumed, whether it be in transit or whether it be in storage; is that not correct?

Dr. SMITH. Well, they are used for a great diversity of purposes: To make foods last longer, to preserve them; to give them a different texture that may, for one reason or another, be attractive; to give them a different color, an artificial color, or perhaps an artificial flavor.

Mr. BUSH. Has it been your experience, when certain of these additives are put together in these foods, that there is any reaction against each other, or do they work together?

Dr. SMITH. I have not any experience on that subject, sir.

Mr. BUSH. That is all.

Mr. WILLIAMS. Before we proceed further, permit me to make a statement at this time.

I think it is quite obvious at this point that it will be impossible to conclude this morning the testimony of Dr. Smith and Dr. Ray, who have come from quite a distance to appear before the committee.

The House meets at 12 o'clock noon on the mutual-security authorization under the 5-minute rule for amendments and, therefore, it would be impossible for the committee to sit this afternoon.

Therefore, I think perhaps we should make the announcement that if we fail to conclude with the testimony of these doctors today, who have come from a great distance, we will open our hearings in the morning with a continuation of their testimony.

And, while we hope it will not be necessary, if it becomes necessary we will attempt to reschedule the witnesses scheduled for tomorrow for a later date which may be convenient for them.

I thought perhaps I should make that announcement for the benefit of the witnesses who are scheduled for tomorrow. I am hoping it will not be necessary; but, if it becomes necessary, I think we can work out a date mutually agreeable to these witnesses and the committee.

Mr. O'Brien?

Mr. O'BRIEN. Doctor, as I understand your statement, you believe that we should provide by law that a chemical which kills a rat or which causes cancer in a rat or a guinea pig or any other animal, should not be permitted to be added to the food consumed by humans, at least until we know more about the effect upon their systems of that particular chemical; is that correct?

Dr. SMITH. Yes, sir.

Mr. O'BRIEN. Do you happen to know how widespread the use of the chemicals you have in mind is at the present time?

Dr. SMITH. Well——

Mr. O'BRIEN. Are there numerous instances of where these chemicals have caused cancer in animals where those chemicals are now being used in processed foods?

Dr. SMITH. The instance that I cited in my testimony just a few minutes ago, where this problem was brought to a test case, was concerned with a pesticide chemical. There is at least one other pesticide chemical that has been described by the Food and Drug Administration laboratories to induce cancer in animals when eaten.

As far as other chemicals in foods, many of the food dyes, coal-tar dyes, have the property of inducing cancer when tested by injection under the skin of animals.

One of the coal-tar dyes that was used in the United States in thousands of pounds annually, it was discontinued just last year, but that dye, which we all thought was safe for many years, was reported in very recent studies to have induced tumors in the intestinal tract and cancer there, when eaten.

Mr. O'BRIEN. Well, you do not know offhand, then, many instances of where additives other than those you have mentioned have caused cancer in the animals when they were tested? What I have in mind is this, Doctor: We know there is a double health problem here—the danger of inducing cancer in humans, and also the desirability of processing which will preserve our food supply.

Do you thnk, if the Delaney bill became law, that it would in effect wreck the processing business, the additive business, if you will? You do not think, do you, that the use of these chemicals is so widespread that it would completely disorganize and destroy the additive business?

Dr. SMITH. The use of carcinogenic chemicals?

Mr. O'BRIEN. I am talking of the chemicals which induce cancer in animals.

Dr. SMITH. No; I do not think that the exclusion of carcinogens would in itself create any serious inconvenience.

The basic problem, it seems to me, is that we cannot know what the long-term effect of any new chemical on human beings will be until those human beings have lived out their life span and we have had a chance to observe them throughout their lives. That means a whole generation of observation.

I cannot really see the justification for legislation which would oblige consumers to accept an endless and unlimited series of artificial chemicals in their food. Why permit the addition to foods of 50 or 150 antioxidants, if 3 or 4 would do? Why use a couple of dozen different emulsifiers, if 2 or 3 would do?

This concept was applied in the matter of the food dyes over 20 years ago. Government and industry people got together and reviewed the matter of the many different artificial colors that were being used in foods, and they sat down and they said, "Well, now, what do we really need?"

Well, they needed a spectrum of colors. They wanted to be able to achieve different shades. All right. They agreed on a limited list of artificial dyes which, in their best judgment, they felt were safe, and they established such a list and everybody then got along perfectly well, as far as the technological needs of the industry were concerned.

Now, that principle of a limited list could easily be extended to other categories of food additives. The antioxidants, the preservatives, the emulsifiers, the other compounds that are necessary for the national distribution of processed foods.

Mr. O'BRIEN. I just have one final question I would like to clarify in my own mind.

Do you think that some people in the food industry have tried to punish people who advocate what you are advocating here this morning? I think you practically stated that.

Dr. SMITH. I have been talking about situations which involve chemical industries. I have not been aware of any of these problems in the food industry at all.

Mr. O'BRIEN. The chemical industry is what I meant to say. You think that there has been a move to punish people who advocate what you are advocating here today, directly or indirectly?

Dr. SMITH. I have observed that scientists who advocate caution in this matter are apt to end up without a job.

Mr. O'BRIEN. You think that goes beyond pure coincidence?

Dr. SMITH. Well, I think that it is hardly likely that the same misfortune could fall out in such a pattern simply by coincidence.

Mr. O'BRIEN. Thank you.

Mr. DOLLINGER. Will the gentleman yield at that point?

Doctor, was that not the cause for your failure to be reappointed to NYU? Did you not indicate that to the committee this morning?

Dr. SMITH. Yes, sir; I did.

Mr. DOLLINGER. In other words, if you do not play ball with some of these large companies, you cannot continue to hold your job, at the

expense, of course, of the health of the consuming public. Would that not be the proper way to put it?

Dr. SMITH. In these cases that have occurred, that is my feeling; yes.

Mr. DOLLINGER. I wonder whether you know of other situations such as yours, giving us the names, if you can, of these doctors who have lost their positions as a result of such a situation? Is that possible to give us?

Dr. SMITH. Yes, sir; I do. I have this material, and I would be, of course, prepared to document anything that I have said.

I would prefer if you did not ask me that question, because I do not feel that this is a problem which applies to any one organization. I would not like to lay a burden upon any one company.

It is a matter of general advance in philosophy that we need here. Industries have made excellent progress in controlling readily demonstrable hazards, but there has been, perhaps very understandably, a reluctance to face up to the facts of the peculiar pharmacology of the carcinogens.

Mr. DOLLINGER. Doctor, I did not want to embarrass you, but I thought if that statement could be given to the committee, without embarrassment, of course, it might establish a pattern, and we are interested to look into that if we can.

You can think the thing over between now and before the committee recesses, not today; and if you think you can do it in good conscience, it might be very helpful to us.

Dr. SMITH. I could do that. I do not know what the customs are here——

Mr. DOLLINGER. Why do you not discuss that with Mr. Delaney, and see what you can do?

Dr. SMITH. I would prefer to give it to the committee for its advice, rather than to mention it in an open meeting where there might be newspaper reporters who would pick up a statement of this sort.

Mr. DOLLINGER. I think we could receive it under those circumstances—can we do that, Mr. Chairman?

Mr. RHODES (presiding). If there is no objection.

Mr. DOLLINGER. Thank you.

Mr. O'BRIEN. I have finished, Mr. Chairman.

Mr. RHODES. Mr. Heselton?

Mr. HESELTON. The last line of questioning interested me very much, particularly in terms of what I understood you to say, Doctor, in the course of your testimony, when you identified 1 individual from New York University, and then went on to mention, I think, at least 2 others whom you did not identify.

I have some questions I would like to ask. I am not a scientist and am not competent in that field, but there are some questions, I think, that should be asked of each of you gentlemen, that is, yourself, Dr. Hueper, and Dr. Ray.

However, I think possibly, in view of the course this hearing has taken, and the likelihood we will have to go to the floor in a few minutes, they should be deferred until after Dr. Hueper and Dr. Ray have given their statements, and then perhaps the three of you would be willing to answer this very short series of questions which I think should be a matter of record before the committee.

Let me ask you this: Were there two other unidentified individuals to whom you referred in your statement, or did I misunderstand you?

Dr. SMITH. I——

Mr. HESELTON. I am not asking you to identify them now.

Dr. SMITH. I have referred to three.

Mr. HESELTON. Three.

Dr. SMITH. Three separate individuals.

Mr. HESELTON. Yes.

Dr. SMITH. Who have found their research or their actual jobs terminated after they became involved in problems of carcinogens of commercial interest.

Mr. HESELTON. Let me ask you this: Did I understand you correctly to suggest that the type of action which I understand you feel may have taken place in some instances, reached as far as into the Food and Drug Administration?

Dr. SMITH. No, sir.

Mr. HESELTON. Without naming any individual.

Dr. SMITH. I do not believe I said that, and I did not mean to give that impression.

Mr. HESELTON. Possibly I misunderstood you.

My feeling is this, Mr. Rhodes, and I am not sure--I regret the chairman had to leave—I suggest to Mr. O'Brien and Mr. Dollinger in particular that, in fairness to everyone involved, we hold a brief executive session to develop what you have asked.

I believe the committee should have this information, even though it be in executive session, and then it will determine whether it should go on the public record.

I think it ought to be a matter, however, referred to Mr. Williams, and probably to Mr. Harris, and I prefer not to pursue that line of questioning until they determine what course of action we should take.

I do not believe—and I am making no prejudgment at all—I do not believe, and I am certain Dr. Smith and I am sure Mr. Delaney would not want to leave any cloud over anyone without documenting the conclusions that they wish to express to us.

On the other hand, I think the committee would be extremely handicapped in handling this legislation unless they had a frank statement of what your conclusions are, and I think that may be a very proper subject of a brief executive hearing, even at 9:30 tomorrow morning, in order to accommodate the gentlemen who have come so far.

May I suggest that you take that up with Mr. Williams and Mr. Harris?

Mr. RHODES. I think, Mr. Heselton, that is a very good suggestion, and I will take it up with Mr. Williams.

I wonder if the doctors could find it possible to stay over until tomorrow?

Dr. SMITH. I can, sir.

Mr. RHODES. How about the other two?

Mr. DELANEY. Yes; I believe both of them will be available tomorrow. They will stay over.

Mr. HESELTON. Then I would like to defer the questions I have.

Mr. O'Brien. Will the gentleman yield?

I think the gentleman has taken the proper position. I do not think any of us would like to feel that there are any persons in this country, whether in industry or anywhere else, who would want to feed people things that would cause cancer. I think perhaps in some instances there is just an area of disagreement, where there is a feeling, "Let well enough alone; let's not pursue this any further, because it might cause us some economic damage."

But it seems to me that if we read our history, we find scientists have been struck down throughout the years because they dared to disagree with the status quo. And whether the committee finally agrees with what you have testified to, Dr. Smith, or not, I personally feel that you are taking a very courageous line.

Dr. Smith. Well, thank you, Mr. O'Brien. I should like to say that I do not feel there is anybody that I know of in the country who deliberately wants to use anything in foods that he honestly would feel in his own mind was dangerous. It is not a question of that at all. We have a very difficult and complicated problem, and there is room for a lot of question and a great deal of further research.

What I am trying to say is that, with the peculiar and unusual pharmacology of the compounds that induce cancer, where they have irreversible effects on cells, we cannot afford to take chances. We cannot let these things get into foods in the thought that, if 3 or 4 more committees consider the thing for 3 or 4 or 5 more years, or 20 more years of laboratory research is done, and it is decided that this was a bad idea, we cannot go back.

Once a carcinogen affects a cell, the removal of that chemical does not mean that all will be well and the cell will not progress to cancer. The effect on the cell is accomplished, and that cell then can go on and multiply, and its descendants go on and multiply and we then end up with a tumor.

Mr. Heselton. Doctor, let me say that, in raising the question as to procedure, I am not suggesting in any way at all that you are not here in good faith, that you are not attempting to offer us the best judgment you can give us.

But, as I have read the bills—and I am afraid Mr. Delaney is not here—but I will not ask you to answer it except in this sense: It is my understanding you have recommended the new bill of Mr. Delaney, H. R. 7798, in terms of the prohibition against the Secretary's approving for use in food any chemical addition found to induce cancer in man or, after tests, found to induce cancer in animals.

That has been the heart of your testimony this morning. If I understand the situation correctly, that was not in Mr. Delaney's bill when it was before the committee in 1956. I think that the questions which obviously remain in the minds of my colleagues, Mr. O'Brien and Mr. Dollinger, and I think are in the minds of all the committee, may deserve some further consideration in executive session by the committee. I am sure you understand it is not intended as any reflection upon you or anybody else in that sense.

You do not have to comment. I just want to make it clear so there would not be any misunderstanding.

Dr. SMITH. I have supported H. R. 7798 because of those particular provisions, but I would like to say it is my belief that H. R. 7798 is a generally good bill in its other aspects.

Mr. HESELTON. Yes, sir.

That is all, Mr. Chairman.

Mr. RHODES. It is now after 12 o'clock, and I am quite sure there will be a quorum call in a few moments. If there is no objection, we will adjourn until 9:30 tomorrow morning.

(Whereupon, at 12:05 p. m., the subcommittee adjourned, to reconvene at 9:30 a. m., Friday, July 19, 1957.)

FOOD ADDITIVES

FRIDAY, JULY 19, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334, New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. The committee will please be in order.

Before continuing with the hearings this morning, I would like to make a brief statement.

The Subcommittee on Health and Science was not entirely unprepared for the line of testimony which was given yesterday by Dr. Smith and which may or may not be continued today by Dr. Ray and Dr. Hueper.

The issues involved are of a scientific nature, and I am sure the members of this subcommittee would not presume to pass upon the merits of the testimony of these expert witnesses.

In anticipation of the controversial nature of these scientific issues, the subcommittee has requested, as previously announced, the National Academy of Sciences to appoint a panel of experts and to suggest an impartial chairman to discuss the scientific background for the chemical-additive legislation before us, including the scientific issues raised by Dr. Smith and other scientists who will testify today.

I am happy to announce this morning that Dr. William E. Darby, head of the department of biochemistry, director, division of nutrition, Vanderbilt University School of Medicine, and chairman of the Food Protection Committee of the National Academy of Sciences, who was suggested as impartial chairman of the panel, has kindly consented to act is this capacity.

Dr. Darby is at the present time in Indonesia, but he will return shortly and the panel hearings have been scheduled for Tuesday, August 6, and Wednesday, August 7. Invitations have gone out to the 18 members of the panel suggested by the Academy, and the names of the members will be made public as soon as acceptances have been received by those invited to participate in the panel discussion.

It is apparent to the Chair that the situation in which this committee finds itself with regard to the safety of chemical additives is not too dissimilar from the situation which arose with respect to the safety of the Salk vaccine in recent years.

The scientific panel recommended by the National Academy of Sciences to discuss the safety of the Salk vaccine presented a balanced

view of the scientific considerations which had to be taken into account in determining whether to proceed with the polio-vaccination program which had been recommended to the Congress by the administration or whether to discontinue vaccinations.

In the case of chemical additives, too, what the committee may need is a cross section of the scientific points of view held by competent scientists in this field. The subcommittee expects that the panel recommended by the academy will present to the subcommittee all of the considerations which must be borne in mind in passing on the safety or the lack thereof of chemical additives.

I might state, also, that we have only 45 minutes this morning in which to take testimony, due to the fact that the House is meeting at 11 o'clock.

On yesterday we heard Dr. Smith, who presented a statement to the committee and then subjected himself to interrogation by members of the committee. We did not complete Dr. Smith's testimony, and if he will come to the stand we would be very glad to hear further from Dr. Smith.

STATEMENT OF DR. WILLIAM E. SMITH, ENGLEWOOD, N. J.—Resumed

Mr. WILLIAMS. Dr. Smith, on yesterday, shortly before the committee found it necessary to adjourn because the House was in session, and at a time when it had become necessary for me to absent myself from the committee, I am informed that some rather startling statements were made by you which may have reflected upon certain people or institutions. If you would care to elaborate further on that, the committee would be glad to hear you.

Also, the Chair will recognize any member of the committee for any questions that he might have. I might state, though, that we have Dr. Ray here, from Florida, who also has come here at great expense to himself, and the committee would like very much to expedite this matter and to hear both Dr. Ray and yourself on anything further that you might care to state to the committee.

So, at this time, the Chair recognizes you, Dr. Smith, for any statement you might care to make.

Dr. SMITH. Thank you, sir.

I had understood yesterday that this matter might be explored in executive session. However, if that is not the case, I feel it is of sufficient importance so that I feel obligated to describe material that has come to my attention in this field.

It is a matter of record that can be demonstrated by reference to the biographies of the men involved——

Mr. DIES. Of whom?

Dr. SMITH. Of the men involved—that four scientists and physicians have lost their appointments after becoming involved in problems concerned with carcinogens of commercial interest.

To begin with, betanaphthylamine, which is considered the most dangerous carcinogen for man, has induced cancer in the bladder in many hundreds of men who have been engaged in its manufacture.

Mr. DINGELL. What was the substance?

Dr. SMITH. Betanaphthylamine. The fact that this substance was able to induce cancer and was responsible for these tumors in men

was confirmed through experiments on animals. These experiments were conducted on dogs, and were done and reported by Dr. William C. Hueper, who at that time was, I believe, assistant medical director for the Du Pont Co.

Now, that was in 1938, when that paper was published. If you look at the record, you will find that in that year Dr. Huepers position with the company was terminated.

Now, this compound is of very real importance for our interests here, because from it are made some of the most widely used food dyes. I understand that more than 100,000 pounds of these dyes are certified for use in food in the United States each year.

Mr. DINGELL. Doctor, may I ask you this question: Are any of these derivatives of betanaphthylamine used as food dyes, and if used as food dyes, do they possess the same properties of producing cancer as the parent substance possesses?

Dr. SMITH. Dyes made from betanaphthylamine are used as food dyes; indeed, yes. Whether they possess the property of the parent substance, we cannot be sure, but I am told that it is exceedingly difficult to make these dyes pure and free of the parent substance, and there is evidence now beginning to appear that these dyes are split to release a carcinogenic substance in the body.

Now, this is a problem that should have been investigated long before the dyes were used; not 20 years after they were used.

Let me give you other instances. A very large program for study of the cancer-inducing properties of chemicals was set up by Dr. Robert Collier Page, who was the general medical director for the Standard Oil Company of New Jersey. Now Dr. Page no longer has his position.

Mr. HESELTON. Do we have his full name?

Dr. SMITH. Dr. Robert Collier Page.

(The following information was later received for the record:)

After reviewing testimony delivered on July 19, 1957, by Dr. William E. Smith, Standard Oil Co. (New Jersey) contacted Dr. Robert Collier Page and received the attached communication, which the company would appreciate having inserted at an appropriate point in the subcommittee record.

JULY 23, 1957.

Mr. STEWART SCHACKNE.
Standard Oil Co. (New Jersey),
New York, N. Y.

DEAR STEW: I was glad to have your phone call last Friday and, naturally, mighty interested in the report out of Washington that a statement had been made before a congressional subcommittee to the effect that I had been obliged to leave Standard Oil Co. (New Jersey) because of my interest in cancer research and that this was opposed by the company. Needless to say, I was astonished and shocked by such an allegation.

You and I know there is not an iota of truth in it, and, in case you receive any inquiries, I am perfectly willing that you should quote me to this effect and make clear that any such allegations are entirely untrue.

I am presently enjoying my capacity as a consultant to Jersey Standard and sincerely hope that it will not be necessary to refer to the above matter again.

Sincerely,

BOB
R. C. PAGE.

Dr. SMITH. In 1951, I think it was, Dr. Arthur Vorwald, who was at that time the director of the Saranac Laboratory, described his discovery that cancer of the lungs could be induced by a chemical, a dust of industrial interest. He no longer has his position. The year

following his discovery, I received a letter from him advising me that he regretted to have to say that he had offered his resignation.

I had a similar experience myself, as I told you yesterday.

Again, as I told you yesterday, a program for study of environmental factors in cancer was initiated by the National Cancer Institute. This program was terminated, and I mentioned that to you yesterday, and I would be glad to submit to you, as a part of my testimony, a letter from the director of that program, documenting the point that I made.

Mr. WILLIAMS. Doctor, may I interrupt you at this point? With respect to that, and since the subject has been brought up again today, on yesterday you testified as follows. This was included in your prepared statement:

> In 1950, the National Cancer Institute of the United States Public Health Service established a program for study of environmental chemical factors in cancer.
>
> Within a few years, a Dr. A. J. Lanza, then director of the Institute of Industrial Medicine at New York University, told me that he had been retained by a group of chemical industries to call upon the Surgeon General and object to studies conducted under this program.
>
> He stated that his objections had been successful, and that all field studies by the National Cancer Institute in this program would be stopped. They were.
>
> A few days later I showed this same gentleman data indicating a cancer hazard for men employed in another industry, that had retained him as a consultant. He advised me to keep out of this problem; and shortly thereafter notified me that my appointment as associate professor of industrial medicine at New York University would not be renewed. It was not renewed.

With respect to the first paragraph that I just read, I made inquiry yesterday of the Surgeon General, and received this letter this morning, which I should like to have included in the record and which I will read at this time.

This letter is dated July 19, 1957, and is over the signature of Dr. L. E. Burney, the Surgeon General, and I quote:

> I appreciate your thoughtfulness in bringing to my attention an excerpt from the testimony of Dr. William E. Smith, of Englewood, N. J., who appeared before your committee yesterday. His statement indicated that a representative from the chemical industries had objected to a program of studies being undertaken by the Public Health Service relating to environmental chemical factors in cancer, and that as a result of this objection all field studies in this program were terminated.
>
> Since I was not stationed in Washington during the period indicated in the statement, it is not possible for me to speak from any personal knowledge of the situation. I can state, however, that on its face the statement is not in conformity with the facts. The Public Health Service has continued its program of field studies involving chemicals suspected of causing cancer and, in fact, has expanded the program of environmental cancer research, both in laboratory and in field investigations.
>
> I am having a thorough exploration made of available information relating to this matter, and shall be able to give you a more complete report at an early date.

And that is signed "L. E. Burney, Surgeon General."

Dr. Smith, there seems to be some differences of opinion as to, between you and the Surgeon General, whether these field studies have or have not been continued.

Mr. DIES. Mr. Chairman, if you will pardon the interruption there, it would be more than a difference of opinion. This witness made the positive, unequivocal statement that all of these studies, this research was stopped.

Now, the Surgeon General says that is not true. Not only has it not stopped but it has been enlarged.

That creates an issue of fact between the witness, who has testified before our committee, who has made a positive statement, and the Surgeon General, who has contradicted flatly that statement.

I think there ought to be some statement by the witness upon what basis he told the committee this was stopped.

Mr. DINGELL. I appreciate the gentleman's interest in that point and I am extremely interested, too, but I do wonder if we are not getting ourselves a little far afield and getting ourselves into a trial of an issue which has very little to do with the legislatiton before this committee.

Mr. WILLIAMS. I was going to make a statement about that.

Mr. DINGELL. And in view of that, Mr. Chairman, may I very respectfully suggest to the Chair that it would be well, particularly in view of the very limited time remaining to us, to concentrate whatever time remains, especially since the witnesses have come so far at their own expense, on getting into the business of whether food additives are dangerous to human beings. If so, whether food additives are being produced, which are dangerous to human beings, and what we should do in the form of reporting out a bill of the type of which there are several before this committee.

Mr. WILLIAMS. Permit me to say at this point that I find myself in agreement with the gentleman from Michigan, one of the very few times I have agreed with him.

Mr. DINGELL. Perhaps the chairman ought to reappraise his position. [Laughter.]

Mr. WILLIAMS. Perhaps.

Dr. Smith, you have, in your testimony, made some rather serious allegations. You have made the flat charge that cancer research or research into this field was stopped.

The Surgeon General has denied this, made a categorical denial. However, reading the last paragraph of the Surgeon General's letter, I note that he says:

> I am having a thorough exploration made of available information relating to this matter, and shall be able to give you a more complete report at an early date.

Doctor, the business before the committee at the moment, of course, is the food-additive legislation. What relationship pressures of one organization or one group of individuals on another group of individuals may have to this legislation has not been made clear to me. I fail to see where those matters might have a bearing on the merits or lack of merit of the legislation before us.

However, I recognize, and I am sure other members of this committee recognize, that the charges that you have made are serious enough to warrant at least an explanation by all parties concerned. And I feel reasonably certain that after the committee has received the more complete report that will be submitted to us by the Surgeon General, that the committee will then want to get together and decide what course of action to take next, with respect to the particular incidents which you have pointed up.

For the moment, though, we would like to proceed, if possible, with respect to the merits of the legislation before us, and to have our testimony confined to that.

I might say, also, that we will keep the record open to all persons and all organizations charged by Dr. Smith in his testimony—in order to permit them to reply to his charges.

And I might say, also, Doctor, that we will keep the record open in case you would like to submit documented evidence or proof of the incidents to which you have referred. We would be glad to receive any additional information that you might care to submit to the committee, dealing with this matter.

Mr. HESELTON. Mr. Chairman, I have no doubt you intended to include an opportunity for Dr. A. J. Lanza, who has been mentioned specifically in Dr. Smith's testimony, to make any reply he wishes to the statement made by Dr. Smith.

I do not know whether he is now director of the Institute of Industrial Medicine at New York University, but whatever his position is, he should be given the opportunity to do so.

Mr. WILLIAMS. I think definitely we should keep the record open to anyone whose name has been mentioned, or anyone even by inference who might be involved in the incidents that have been reported to the committee, including Dr. Smith and his associates, if they desire to elaborate further on the matter.

(The following letter was received for the record:)

NEW YORK UNIVERSITY-BELLEVUE MEDICAL
CENTER OF NEW YORK UNIVERSITY,
INSTITUTE OF INDUSTRIAL MEDICINE,
New York, N. Y., July 22, 1957.

The Honorable JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce, House Office Building, Washington, D. C.

DEAR MR. WILLIAMS: With respect to the testimony of Dr. W. E. Smith on July 18, 1957, before the Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce, Dr. Smith stated that I had been retained by a group of chemical industries to call upon the Surgeon General and object to studies conducted under the program established by the National Cancer Institute of the United States Public Health Service. There is no truth in this statement.

As a matter of fact, during the years referred to in Dr. Smith's testimony, I was privileged to encourage several Public Health Service studies in industry. One such study was a cooperative effort between the chromium industry and the Public Health Service. This led to the first publication in this country showing lung cancer in the chromium industry (Machle and Gregorius, Public Health Reports, vol. 63, pp. 1114–1127, 1948). This study was continued by the Public Health Service on an industrywide basis and led to a further publication (Public Health Service Publication No. 192, Health of Chromate Workers). Again, in the period 1952–55, the Public Health Service conducted field studies in the diatomaceous earth industries. This study grew out of conferences between myself, the Public Health Service, the California State Board of Health, representatives of industry, and others interested. The report of this is in preparation and will shortly appear as an official Public Health Service publication.

At no time have I ever advised the Surgeon General of the Public Health Service that any industrial field study be discontinued.

For the record, I would like to insert a categorical denial of Dr. Smith's implications that his nonreappointment was in any way related to his interest in cancer hazards in industry. Dr. Smith's nonreappointment was based on the judgment that his training and competence made him unsuitable for continued responsibility on the faculty of New York University.

Very truly yours,

ANTHONY J. LANZA, M. D.,
Professor Emeritus, Industrial Medicine.

Dr. SMITH. Thank you, sir. I would welcome that.

I would like, if I may, to have one more word in response to Mr. Dies' point that there seems to be a discrepancy between my testimony

yesterday and the statement contained in the letter received this morning from the Surgeon General.

I should say that the situation that I referred to occurred in, I think it was 1951, which was prior to the appointment of the present Surgeon General. And the letter from the director of the program that I referred to, which was at the National Cancer Institute, I have here. And I offer it for the record and I would like to submit it for the record.

I would also like to submit for the record another letter from a physician who was present at a meeting with the medical director of the Du Pont Co., and who states that he recalls that that officer said that Dr. Hueper had been discharged by that company shortly after showing that betanaphthylamine induced cancer.

I would be glad to answer any further questions at this time.

Mr. WILLIAMS. Might we take a look at those documents?

Mr. O'BRIEN. I think the Chair has stated very fairly the feeling of the other members, or this member of the subcommittee. We do have a major problem here, a major question, and if we are to go off on a complete tangent we would not reach our ultimate goal.

I would like to make this additional suggestion: Where any of these allegations refer to any public agency, that the matter be respectfully referred to the Special Committee on Legislative Oversight which has been created at this session.

Mr. HESELTON. I want to further reserve the right to object. I do not know whether we should do that or not.

I suggest that this should be decided in executive session.

Mr. WILLIAMS. With respect to the inclusion of these letters in the record, is there objection on the part of any member of the committee?

Mr. HESELTON. Yes. That one we agreed to——

Mr. DINGELL. I would like to associate myself with the remarks of our colleague, Mr. Heselton, on the determination of this matter in executive session, Mr. Chairman.

Mr. WILLIAMS. I think that is a matter that should be considered in executive session. That is a matter of procedure and policy.

The question now is inclusion of these letters in his testimony.

Mr. DINGELL. Mr. Chairman, may I be recognized for the purpose of asking several questions of the witness during the time we are determining these matters?

Mr. WILLIAMS. You may proceed.

Mr. DINGELL. Doctor, I have been interested in your remarks, and I was just wondering, since our time is very short, would you care to elaborate on the use of carcinogens, particularly of substances either known or strongly suspected to be carcinogens in food, giving specific attention to those items which are or might be reasonably expected to produce cancer in the human body; what those substances are, if they are used, how they are used, and how many of them there are, if you possibly could, this morning.

Dr. SMITH. This was the subject of the two last issues, which are big, thick volumes, of the Acts of the International Union Against Cancer. It was the particular subject of a meeting held by the union in Rome last year, and the chairman of that session is available to you here for testimony.

He is Dr. William C. Hueper, and I understand he will offer his testimony.

I think that it would be more appropriate if he would handle this matter.

Mr. DINGELL. All right.

Doctor, may I ask if there is anything further that you would care to tell this committee this morning?

The reason I say that is we have another prominent medical man here from Florida, and we are anxious to hear him.

Dr. SMITH. I would only like to say that in all of my comments this morning my personal experience is of no importance to anybody except myself. It happens that I have devoted 20 years to medical research. I have a wife and three children. I got entangled in this problem of commercial carcinogens, and the result is that I have no job and no prospect of ever being able to continue in the field to which I have devoted my scientific career.

Now, that is of no particular importance. I am perfectly expendable; but when I see one man after the other who is engaged in this kind of research end up pushed out of his work or out of his career, I believe that this is a problem that is of importance for the public health. And it is for that reason that I have spoken openly as I have today.

Mr. WILLIAMS. I believe members of the committee have looked over these documents that were submitted.

Is there objection to the inclusion—to permitting Dr. Smith to include these as part of his testimony?

The Chair hears none, and you will be permitted to include these as part of your testimony, Doctor.

However, I think it might be well for you, in the case of one of these letters, to identify the author of the letter, E. S. Ross.

Dr. SMITH. Dr. E. S. Ross is the chief medical director of the Brotherhood of Railroad Trainmen.

Mr. WILLIAMS. Is he presently in that capacity?

Dr. SMITH. Yes. He is here this morning.

Mr. WILLIAMS. He has offices in Washington, D. C.?

Dr. SMITH. His office is in Cleveland.

Mr. WILLIAMS. This letter was addressed from Washington yesterday.

If there are no objections, these will be included in the record.

(The letters referred to are as follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
Bethesda, Md., August 24, 1955.

Dr. WILLIAM E. SMITH,
New York University Postgraduate Medical School,
New York, N. Y.

DEAR DR. SMITH: I have your comments on my editorial on "Silicosis, Asbestosis, and Cancer of the Lung" and your inquiry concerning my more recent activities in field studies on occupational cancer problems.

The Canadian case referred to in the editorial applies to the claims made by the widow of a Mr. Maurice Labbé, 805 St. Catherine Street, Trois-Rivières, Quebec, Canada. The legal procedures in regard to this case which were negotiated before the Workmen's Compensation Commission of Quebec took place during the last few months of 1951 and the first few months of 1952. The

special legal adviser to the minister of labour of Quebec was Mr. Louis F. Cantin, 225 Grande-Allé, Quebec, Province of Quebec, Canada.

My activities in fieldwork on environmental cancer were discontinued during the latter part of the summer of 1951 when I was requested to stop such activities and have no further contacts with industry or State health departments in matters of environmental and occupational cancer. This event was brought about by a complaint, as I was officially told, about my activities in regard to studying conditions bringing about lung cancers among workers employed in the chromate industry, made to my superiors in Washington in behalf and in the interest of the American chromate industry by Dr. Lanza, as its medical representative. Dr. Lanza apparently acted in the role of a lobbyist, because in a telephone conversation on July 25, 1951, I had in regard to this matter with Mr. O. F. Tarr, vice president, Mutual Chemical Co., I was told Dr. Lanza had taken this step in behalf of the American chromate industry.

The immediate reason for this complaint was provided by a copy of a manuscript prepared by Dr. Mancuso and myself on observations made in Ohio on cancer and health hazards among chromate manufacturers which I had given before its publication in Industrial Medicine and Surgery to Mr. Tarr, who had forwarded this copy to Dr. Lanza. As a result of this event, it was strongly suggested to me to take my name off these manuscripts and it is for this reason that my name is lacking on the second paper dealing with the joint investigations on health hazards among chromate manufacturers conducted by Dr. Mancuso and myself (Occupational Cancer and Other Health Hazards in a Chromate Plant: A Medical Appraisal. II. Clinical and Toxicologic Aspects. Ind. Med. & Surg. 20: 393–407, (September) 1951).

Due to these lobbying activities of Dr. Lanza, not only my field studies have come to an end since 1951 but there was for some time serious interference even with my experimental work in the field of occupational cancer because I was not able to continue for some time my cooperative work with the Mutual Chemical Co. on blood reactions in chromate manufacturers. It was only after a rather long delay that I finally succeeded in reactivating this problem.

I can say that during the lifetime of Mr. Tarr, I had enjoyed the most harmonious, cooperative relations between the Mutual Chemical Co. and the carcinogenic studies section—as my section was called at that time. It is my belief, however, that, through the intervention of Dr. Lanza, not only the interest of America industries with cancer hazards to workers employed in these industries, but of the American people at large, and of the American medical profession, was seriously damaged.

Sincerely yours,

W. C. HUEPER, M. D.,
Chief, Environmental Cancer Section,
National Cancer Institute.

WASHINGTON, D. C., *July 18, 1957.*

Dr. WILLIAM E. SMITH,
Englewood, N. J.

DEAR DR. SMITH: In response to your inquiry, I do recall a meeting with you and the medical director of the Du Pont Co., who was, I believe, a Dr. Fleming. I recall he said that Dr. W. C. Hueper had been discharged by that company shortly after showing that betanaphthylamine induced cancer. This meeting was in New York toward the end of 1955.

Very sincerely,

E. S. ROSS, M. D.

Mr. WILLIAMS. Are there any further questions of Dr. Smith?

Mr. O'BRIEN. Mr. Chairman, may I suggest in view of the time, we hear from Dr. Ray?

Mr. WILLIAMS. Thank you, Dr. Smith.

I might repeat that if you have additional information that you would like to submit to the committee, we would be very happy to receive it.

Dr. SMITH. Thank you.

Mr. HESELTON. Mr. Chairman, may I request that Dr. Smith supply at his convenience the chronology of his association with Harvard

Medical, Rockefeller Institute of Medical Research, Sloan-Kettering Institute, and New York University?

Mr. WILLIAMS. Did you hear the question?

Dr. SMITH. No, sir.

Mr. HESELTON. Would you be willing, at your convenience, Doctor, to simply supply the dates of your association with Harvard Medical School, Rockefeller Institute of Medical Research, the Sloan-Kettering Institute for Cancer Research, and New York University?

Dr. SMITH. I was in bacteriology at the Harvard Medical School from 1940——

Mr. HESELTON. I do not mean you should do it now orally. Will you supply it for the record?

Dr. SMITH. Yes, sir.

Mr. HESELTON. Thank you.

Mr. WILLIAMS. Thank you, Dr. Smith.

(The information requested follows:)

ENGLEWOOD, N. J., *August 26, 1957.*

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science,
House Office Building, Washington, D. C.

DEAR MR. WILLIAMS: At the end of my testimony before your committee on July 19, Mr. Heselton asked me to supply for the record the chronology of my association with various institutions. This is as follows:

In 1938 I received the degree of doctor of medicine from the Johns Hopkins University and became a research fellow in bacteriology at the Harvard Medical School. From December 1938 until November 1940 I was laid up with tuberculosis. From November 1940 to September 1941 I was a fellow in medicine at the Massachusetts General Hospital, from September 1941 to September 1943 an assistant in bacteriology, Harvard Medical School.

From September 1943 to September 1947 I was assistant in pathology at the Rockefeller Institute for Medical Research, and from September 1947 to September 1949 associate at the Sloan-Kettering Institute for Cancer Research. I was assistant professor of industrial medicine at New York University from September 1949 to July 1953, thereafter associate professor until June 1956. I now have a fellowship for study of nutrition in relation to cancer awarded by the American Academy of Nutrition.

Please allow me to express my appreciation for the courtesy extended me to appear before your committee.

Respectfully yours,

WILLIAM E. SMITH, M. D.

(The following letter, regarding the above testimony, was later received for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
Washington, D. C., October 11, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science,
Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR MR. CHAIRMAN: In my letter of July 19 concerning testimony before the subcommittee by Dr. William E. Smith of Englewood, N. J., to the effect that studies of "environmental chemical factors in cancer" had been terminated by the Public Health Service because of industry opposition, I offer to provide you with information in support of my belief that Dr. Smith's statement was not in conformity with the facts. I am pleased to supply you now with a report on our environmental cancer research program which I believe will supplement and clarify the record with respect to the development of this important activity which for a number of years has merited continued congressional interest and support.

Studies of environmental cancer—those external and internal influences which can induce cancer in experimental animals and in man—were started as a definite program at the National Cancer Institute of the National Institutes of Health in 1948 when a new section on environmental cancer was started under Dr. Hueper. The activity gradually expanded. Work was carried on in the field, and a modest laboratory was established at Georgetown University where we rented 2 rooms and 2,500 square feet of space. In the spring of 1952, 4 professional people, including Dr. Hueper and 2 clerks, were in a Cancerigenic Studies Section and the laboratory at Georgetown had 2 scientists and 6 supporting staff, also under Dr. Hueper's direction.

Reorganization of the increasingly important environmental cancer program was undertaken in 1952 which enlarged it and gave it greater diversification. This trend has continued up to the present time. It is not true that the Public Health Service was persuaded by representatives of industry to terminate or curtail its environmental cancer field studies.

Prior to the 1952 reorganization, the Cancerigenic Studies Section of the National Cancer Institute had been concerned, under the direction of Dr. W. C. Hueper, with the general problem of the relation of environmental factors to cancer. Its activities included the planning of and collaboration in occupational cancer surveys, consultation services, and laboratory research. Technical assistance and consultation in relation to occupational cancer were provided to State health departments, medical schools, and various Federal agencies. Studies of carcinogenic hazards in manufacturing were also undertaken in cooperation with several industries. In May 1952, a new section designated as the Cancerigenic Field Studies Section was established under Dr. Hueper to concentrate on epidemiological environmental cancer surveys. The name of the original Cancerigenic Studies Section was then changed to Cancerigenic Research Studies Section, to concentrate on laboratory research in enviromental cancer. As the organization of this work progressed, the Cancerigenic Research Studies Section was transferred, in October 1952, to the Research Medicine Branch of the National Cancer Institute, and the new Cancerigenic Field Studies Section was redesignated the Field Studies Section of the Cancer Control Branch. The professional staff of the Field Studies Section had been augmented to carry out field investigations in occupational and environmental cancer, with special emphasis on occupational factors related to lung cancer. Plans were also laid, however, to pursue field studies on tobacco, nickel, asbestos, radium, radioactive water, minerals in nonuranium mines, and cigarette smoking, in cooperation with various organizations throughout the country.

The field studies which originally were the responsibility of Dr. Hueper, have remained in the Field Investigations and Demonstrations Branch, formerly the Cancer Control Branch, under Dr. Raymond F. Kaiser, while the laboratory studies continue to be directed by Dr. Hueper under the Associate Director of Research for the National Cancer Institute. The primary purpose of this division of enviromental cancer studies was to distribute the projects properly within the organizational structure which the National Cancer Institute was evolving to administer its growing program.

Another factor involved in the 1952 reorganization of environmental cancer studies was the matter of proper adjustment between the research work of the National Cancer Institute and the occupational health activities of the Public Health Service's Bureau of States Services. A careful definition of program responsibilities, with particular reference to activities of these two branches of the Service which involve cooperation with State agencies and with industry, had to be worked out.

Since the reorganization of environmental cancer studies in 1952, this area of the National Cancer Institute's research program has steadily expanded both as to grant-supported and direct operations, with the continued support of Congress and the cooperation of industrial interests, State health departments, medical schools, Federal agencies, labor organizations, and other groups.

Under our grants program, we are at present supporting 34 projects dealing with environmental cancerigens in 30 separate research institutions, at an annual cost of $420,195. (A list of current pertinent research studies supported by grants is presented in attachment I.)

Our laboratory work at the National Cancer Institute in Bethesda has been increased with an expansion of facilities and increase of staff since 1952. In this program, under Dr. Hueper's direction, projects on chemical causes of cancer are being conducted. The present staff consists of 14 persons occupying

almost double the floor space available in 1952 and utilizing equipment valued at $350,000. (A list of the projects reported in 1956 for this laboratory is presented in attachment II.)

Field studies in environmental cancer have been steadily expanded. We now have 40 investigators, scientists, engineers, epidemiologists, statisticians and clerks, exploring many facets of the environmental cancer problem among definable groups of the human population. University scientists have been supported to an increasing degree through field investigation grants. (A list of pertinent current direct operational field projects is presented in attachment III, and a list of pertinent field investigations grants is presented in attachment IV.)

The National Institutes of Health at Bethesda has been the scene, on two occasions since 1952, of meetings of industrial medical directors for discussion and advice on environmental cancer research. The Cancer Control Committee, which screens applications for field investigation grants and advises the National Cancer Institute on program, has had, since its inception, a subcommittee on environmental cancer to review the field and recommend activities in need of support. In addition to scientific papers on chemical hazards and other environmental cancer subjects published regularly by National Cancer Institute scientists and grantees, the Public Health Service has discussed these studies freely before appropriations subcommittees and other committees of Congress over the years. Moreover, special publications, such as the progress report represented by attachment V, and a public health monograph by Dr. Hueper entitled "Environmental Causes of Cancer of the Lung," have been issued by the Service.

In summary, this program was inaugurated on a very modest scale in 1948, with Dr. Hueper in charge of both the laboratory research and the field study program. In 1952 the program was reorganized, with the laboratory research program remaining under the direction of Dr. Hueper and the field study program assigned to the direction of Dr. Kaiser. Since that time both parts of the program have been expanded, so that each is substantially larger today than the combined program was at the time of the reorganization. While Dr. Hueper's responsibilities for the field studies program were terminated by the reorganization, the program itself was continued and expanded under Dr. Kaiser's direction.

I trust that this information will serve to correct any impression left with the subcommittee by Dr. Smith's testimony that environmental cancer studies have been discontinued or curtailed by the Public Health Service. On the contrary, the steps I have described were taken to produce optimum results with the staff and facilities at our disposal. This is, in fact, an area of our cancer-research effort which, in my estimation, will continue to demand the attention and emphasis that we are giving to it.

Sincerely yours,

L. E. BURNEY, *Surgeon General.*

ATTACHMENT I

NATIONAL CANCER INSTITUTE

Research grants in chemical carcinogenesis, fiscal year 1957

Institution and grant No.	Investigator	Project title	Amount
Baylor University, Houston, Tex., CY-2462(C2)	A. Kirschbaum	Role of ovarian and adrenal cortical secretion in growth and genesis of mouse mammary cancer.	$13,512
Boston University, Boston, Mass.: CY-3135	H. M. Lemon, H. H. Wotiz	The biosynthesis, transport, and metabolism of steroids in relation to endocrine-stimulated cancers.	34,500
C-3406	C. J. Kensler	Metabolic aspects of chemical carcinogenesis	13,665
University of Buffalo, Buffalo, N. Y., C-2122(C3)	L. A. Mirand	Carcinogenic activity of steroid hormones, reference to adrenal steroids.	12,489
Cedars of Lebanon Hospital, Los Angeles, Calif.: C-2012(C3)	H. Sobel, J. Marmorston	Investigations in certain phases of chemical oncology	12,305
C-2399(C2)	H. I. Hadler	Mechanism of carcinogenic action of hydrocarbon 9,10-dimethyl-2-benzanthracene.	7,613
Children's Medical Center, Boston, Mass., C-2107(C3R) M. and G.	F. D. Ingraham, E. A. Bering, Jr.	Investigation of new plastics for use in neurosurgery and general surgery.	5,324
University of Colorado, Denver, Colo., C-1820(C2)	R. A. Huseby	Quantitative relationship of estrogen administration to mammary-gland development and mammary carcinogenesis in mice.	4,979
Columbia University, New York, N. Y., C-1620(C5)	B. S. Oppenheimer	Processes involved in carcinogenesis by polymers	32,736
Detroit Institute of Cancer Research, Detroit, Mich., C-2979.	W. L. Simpson, H. S. Zackheim	Species differences in response to chemical carcinogens. Role of sebaceous glands.	6,992
Duke University, Durham, N. C., C-1741(C4)	S. Rogers	Conditionality of tumor production (urethane)	11,479
Hektoen Institute for Medical Research, Chicago, Ill., 3-2030(C3).	H. Popper	Tissue changes produced by prolonged administration of ethionine, specifically, the production of hepatic tumors.	7,417
University of Illinois, Urbana, Ill., C1932(C3)	F. A. Kummerow	Possible carcinogenic activity of polymerized fats	6,388
Long Island Jewish Hospital, New Hyde Park, Long Island, N. Y., CY-3110.	H. D. Isenberg, J. Berkman	The site and mode of action of urethane	6,980
Massachusetts Memorial Hospital, Boston, Mass., CY-2900(R).	H. Mescon	Controlled evaluation of the factors concerned with the metabolism of steroids by human skin, with particular reference to precancerous and cancerous lesions.	12,959
Michael Reese Hospital (Medical Research Institute), Chicago, Ill., C-248(C11).	A. Tannenbaum	Exploration of mechanisms of carcinogenesis through nutritional investigation.	12,990
University of Minnesota, Minneapolis, Minn: C-2571(C2)	H. R. Gutmann	Research on the mechanism of action of carcinogenic aromatic amines.	25,473
C-3322	R. J. Gorlin, N. H. Rowe	Effect of vitamin A deficiency upon cancer induction	5,500
University of New Mexico, Albuquerque, N. Mex., C-1595(C4).	G. H. Daub	Synthesis and properties of 1-, 7-, 8-, 9-, and 10-monomethyl-3,4-benzpyrenes and some di- and trimethyl-3,4-benzpyrenes. Synthesis and properties of 1-, 7-, 8-, 9-, and 10-monomethyl-3, 4-benzpyrenes and some di- and tri-methyl-3,4-benzpyrenes.	5,130
New York University, New York, N. Y., C-3311	M. Kuschner, N. Nelson, S. Laskin	The experimental induction of bronchogenic carcinoma by compounds of chromium.	8,038

ATTACHMENT I

NATIONAL CANCER INSTITUTE

Research grants in chemical carcinogenesis, fiscal year 1957—Continued

Institution and grant No.	Investigator	Project title	Amount
Alton Ochsner Medical Foundation, New Orleans, La., CY-3364.	A. Segaloff	Hormones and neoplasia	23,825
Ohio State University, Columbus, Ohio, C-483	M. S. Newman	Physical-chemical studies on cancer-producing hydrocarbons	6,210
College of Osteopathic Physicians and Surgeons, Los Angeles, Calif., C-3077.	M. H. Simmers	Carcinogenicity of paving petroleum asphalt	10,373
Palo Alto Medical Research Foundation, Palo Alto, Calif., C-2869.	D. A. Salzberg	Riboflavin-azo dye relationships in azo dye carcinogenesis	13,880
Medical College of South Carolina, Charleston, S. C., C-474(C9).	K. M. Lynch	Lung tumors	4,970
University of Texas, Galveston, Tex., C-1469(C4)	R. H. Rigdon	Tumors in white Peking ducks treated with methylcholanthrene	5,324
University of Utah, Salt Lake City, Utah, C-307 (C9)	L. T. Samuels, W. G. Wiest	Metabolism of steroids and its relation to carcinogenesis	20,974
Medical College of Virginia, Richmond, Va., C-1541 (C5)	C. C. Clayton	Role of minerals in carcinogenesis	5,612
University of Wisconsin, Madison, Wis., C-1132 (C6)	C. Heidelberger	Metabolism of carcinogens labeled with radioactive carbon	12,305
Institut Pasteur, Paris, France:			
C-524 (C9)	A. Lacassagne	Theoretical and experimental study of the mechanism of carcinogenesis by conjugated molecules.	15,676
C-3065	C. Moser	Theoretical investigations on carcinogenic activity	23,460
Laboratoire de Chimie Theorique, Paris, France, CY-3073	B. Pullman	Electronic structure of molecules and chemotherapy of cancer	7,920
University of Helsinki, Helsinki, Finland, C-2930	K. Setala	Mechanism of tumor promotion in experimental chemical skin carcinogenesis in mice and rabbits.	15,000
Indian Cancer Research Center, Bombay, India, C-1648 (C4).	V. R. Khanolkar	Chemical analysis of varieties of Indian tobacco, biological testing of purified fractions or isolates for carcinogenicity, and biological changes in tissues during course of tumor development.	8,137
Total (34 grants)			420,195

ATTACHMENT II

Attachment II

National Cancer Institute

Intramural research studies in chemical carcinogens, calendar year 1956

Principal investigator	Project title	Organizational unit
Dr. E. J. Lethco	Studies on possible cancer hazards related to use of food dyes	Associate Director in Charge of Research.
Dr. J. H. Seipel	Macromolecular polymers as carcinogenic agents	Do.
Dr. W. C. Hueper	Macromolecular polymers as carcinogenic agents: (*a*) Polyvinyl pyrrolidones; (*b*) dextrans; (*c*) other natural and synthetic polymers (polyvinyl alcohol, polysilicones, silica, methyl cellulose, ethyl cellulose.	Do.
Dr. W. C. Hueper	Carcinogenic studies on petroleum substitutes and synthetic liquid fuels; II Bergius oils and Fischer-Tropsch oils; III carcinogenicity of shale oil fractions of low boiling point and free of 3,4-benzpyrene.	Do.
Dr. W. C. Hueper	Experimental studies in metal cancerigenesis: (*a*) Uranium; (*b*) chromium, chromite ore, chromite roast; (*c*) nickel.	Office of the Associate Director in Charge of Research.
Dr. C. H. Grogan	Experimental studies in metal cancerigenesis, chromium	Do.
Dr. W. C. Hueper	Carcinogenic studies on food additives and contaminants: (*a*) Studies on carcinogenic water pollutants—Carbon adsorbate from effluents of a coke plant and of an oil refinery; (*b*) Carcinogenic studies on aromatic amines and food dyes, experimental and environmental aspects.	Do.
Dr. H. J. Cahnmann	Polynuclear aromatic hydrocarbons in oysters	Do.
Dr. M. Kuratsune	Polycyclic aromatic hydrocarbons in roasted coffees and coffee soots	Do.
Dr. W. C. Hueper	Medicolegal and public-health activities and considerations on occupational, environmental and traumatic cancers.	Do.
Dr. W. C. Hueper	Studies on occupation and environmental respiratory cancer hazards caused by the inhalation of carbonaceous air pollutants (coal tar, petroleum asphalt, cutting oil, coffee roast soot).	Do.
Dr. H. J. Cahnmann	Evaluation of various adsorbents elution methods for the chromatographic fractionation of polynuclear aromatic hydrocarbons.	Do.

Attachment III

National Cancer Institutes

Field studies by Field Investigations and Demonstrations Branch

Epidemiology and etiology of cancer, calendar year 1956

Investigators	Project title	Location of project or source material
Miriam D. Manning, M. D	Clinical and environmental study of mothers of children with malignancy other than hemotopoietic.	Boston, Mass.
Victor E. Archer, M. D.; James W. Egan, M. D.; Marian Erjavec, R. N.	Study of occupational backgrounds of hospitalized cases of lung and bowel cancer, leukemias, and primary malignant tumors of bone, in males over the age of 25 years.	Salt Lake City, Utah.
Victor E. Archer, M. D.; Pope A. Lawrence; James W. Egan, M. D. (in cooperation with occupational health program, PHS).	Cancer occurrence in uranium miners of the Colorado Plateau	Do.
Victor E. Archer, M. D. (in cooperation with radiological health program of PHS).	External radiation exposure of uranium miners as related to cancer occurrence	Do.
Victor E. Archer, M. D.; James W. Egan, M. D.; Marian Erjavec, R. N.; Pope A. Lawrence.	Study of the cancer experience of nonuranium hard rock miners in the Rocky Mountain area	Do.
Pope A. Lawrence, Benjamin E. Carroll	Cancer among railroad workers in certain occupations, retrospective phase	Cleveland, Ohio.
Do	Types of cancer among railroad employees—forward-going phase beginning January 1956	Do.
Do	Cancer as a cause of death and disability in railroad workers	Chicago, Ill.
Pope A. Lawrence, Victor E. Archer	Health survey of personnel employed in baths using radioactive water	Small community in Midwest.
Pope A. Lawrence, Benjamin E. Carroll, P. Morgan, M. D.	Cancer experience in community population exposed to unusual radon gas concentration	Do.
Pope A. Lawrence, Ruth Taylor, M. D., Marian Erjavec, R. N.	Survey of cancer mortality in West Virginia	State Health Department, West Virginia.
Pope A. Lawrence, K. Beck, William Lloyd	Geographic distribution of respiratory cancer mortality in 15 selected States: West Virginia, Virginia, Maryland, Pennsylvania, Ohio, Kentucky, North Carolina, Missouri, Arkansas, Louisiana, Arizona, Utah, Colorado, New Mexico, and Montana.	National Office of Vital Statistics.
Pope A. Lawrence	Geographic distribution of cancer in the United States	Bethesda, Md.
Pope A. Lawrence, Henry Greenville, William Chen, M. D.	Geographic and environmental factors in cancer mortality in Washington County, Md	Hagerstown, Md.
Pope A. Lawrence, Benjamin E. Carroll, Ruth Taylor, M. D.	Geographical incidence of cancer of major sites in upstate New York	New York State Health Department, Albany, N. Y.
Ruth Taylor, M. D., Benjamin E. Carroll, William Lloyd.	Cancer mortality in several selected population groups in New England	Boston, Mass.
R. J. Kaiser, M. D., H. F. Dorn, William S. Baum, M. D.	The incidence of respiratory cancer and other major diseases among World War I veterans in relation to their smoking habits.	Bethesda, Md.
John Vander, M. D., H. F. Dorn	Frequency of occurrence of cancer and other major diseases among occupational groups covered by a statewide unemployment insurance.	Providence, R. I.
Philip Morgan, M. D., W. S. Baum, M. D., P. A. Lawrence, Marian Erjavec, R. N.	Etiology of lung, laryngeal, and bladder cancer in New Orleans, La.	New Orleans, La.
John E. Dunn, Jr., M. D.	Evaluation of death certificate reliability as source of environmental cancer information	Berkeley, Calif.
William R. Vogler, M. D.	Cancer registry program	Emory University, Atlanta, Ga.
Lester Grinspoon, M. D., John E. Dunn, Jr.	Excess lung cancer among Mexican females	Los Angeles, Calif.

John E. Dunn, Jr., M. D.	Evaluation of death certificate reliability as source of environmental cancer information	Berkeley, Calif.
William R. Vogler, M. D.	Cancer registry program	Emory University, Atlanta, Ga.
Lester Grinspoon, M. D., John E. Dunn, Jr., M. D.	Excess lung cancer among Mexican females	Los Angeles, Calif.
Lester Grinspoon, M. D.	Study of nonneoplastic and neoplastic changes in the respiratory mucosa of man, and the external factors which may have a relationship to these changes.	Do.
John E. Dunn, Jr., M. D.	Occupation and lung cancer	Berkeley, Calif.
Do	Relation of smog to lung cancer	Los Angeles, Calif.
B. E. Carroll, William Haenszel	Cancer mortality among Catholic brothers and sisters in several teaching orders in the United States.	Boston, Mass.
C. D. McClure, M. D.	Epidemiology of cancer of the lung, Pittsburgh field study	Pittsburgh, Pa.
A. G. Gilliam, M. D., B. K. Milmore, M. D., Robert L. Smith, M. D.	Cancer in a closed population, exposed to gasoline engine exhaust fumes	Bethesda, Md.
Clarence Salsbury, M. D., William J. Pendergrast, M. D., B. K. Milmore, M. D., A. G. Gilliam, M. D.	Studies in geographic and racial distribution of cancer	Do.
B. K. Milmore, M. D., A. G. Gilliam, M. D.	Research in epidemiologic method	Do.
A. G. Gilliam, M. D., B. K. Milmore, M. D., Robert L. Smith, M. D.	Stimulation of epidemiological research in nonservice agencies and development of sources of field data suitable to NCI for answering specific epidemiological questions.	Do.

ATTACHMENT IV

NATIONAL CANCER INSTITUTE

Selected list of field investigations grants relating to environmental cancer research, fiscal year 1957

Institution and grant number	Investigator	Project title	Amount
Arizona State Department of Health, CS-9489	Dr. Clarence G. Salsbury	Navaho cancer research project for 1957	$34,400
University of Southern California, Los Angeles, Calif., CS-9156 (C 5).	Dr. John W. Mehl, Dr. Paul Kotin, Dr. Hugh A. Edmondson.	Investigation of potential carcinogenic environmental compounds	45,276
Stadfond University, San Francisco, Calif., CS-9376 (C)	Dr. Henry S. Kaplan	The epidemiology of acute leukemia in childhood	8,000
Colorado State Department of Public Health, CS-9422	Dr. R. L. Cleere	A study to develop analytical techniques to be used in correlating radioactivity in urine and the respiratory exposure of miners to radon and radon daughter products.	3,888
Connecticut State Department of Health, Hartford Conn., CS-9437 (C).	Dr. Matthew H. Griswold	Studies in cancer epidemiology based on Connecticut cancer register	15,000
Yale University School of Medicine, New Haven, Conn., CS-9073 (C 7).	Dr. J. Wister Meigs	Studies on 4,4' diaminodiphenyl (benzidine) and some of its metabolites; application to industrial hygiene program.	15,000
Garfield Memorial Hospital, Washington, D. C., CS-9263 (C 4).	Dr. Theodore Winship	Study of carcinoma of the thyroid in children under 15 years of age	1,296
Georgetown University Hospital, Washington, D. C., CS-9394 (C).	Dr. Benedict J. Duffy, Jr	Effect of chronic X-radiation on the human thyroid gland	497
National Academy of Sciences-National Research Council, Washington, D. C., CS-9409 (C).	Dr. Bernard M. Cohen, Dr. Paul E. Steiner, Mr. Seymour Jablon, Dr. Robert Schrek.	A study of cancer incidence in veterans	16,070
Chicago Medical School, Chicago, Ill., CS-9212 (C4)	Dr. Phillipe Shubik	Methodology for studying environmental cancer hazards	35,985
University of Kansas Medical School, Kansas City, Kans., CS-9441 (C).	Dr. Frank A. Mantz	Cytologic examination of the sputum as a screening procedure for carcinoma of the lung.	25,357
Harvard College, Cambridge, Mass., CS-9430	Dr. Leonid S. Snegireff	Epidemiological study of neoplasia in persons who received X-ray therapy for enlarged thymos gland in childhood.	9,401
St. Elizabeth's Hospital, Brighton, Mass., CS-9402 (C)	Dr. Susan Butler	The incidence of carcinoma of the breast in nuns	7,178
Health Research, Inc., New York: CS-9408	Dr. Abraham Lilienfeld, Dr. Wendell Ames, Dr. Morton Levin.	Field study of the distribution of tobacco habits and other selected characteristics associated with various types of cancer in the population of Erie County, N. Y.	23,304
CS-9429	Dr. Constance Lenore Simpson	Investigation of late effects of radiation to the head and neck in children.	4,679
CS-9429 (C)	do	do	4,563
State University of New York, Downstate Medical Center, Brooklyn, N. Y., CS-9435.	Dr. Brian MacMahon	Studies of the epidemiology of leukemia and other neoplastic disorders.	12,456
University of Oklahoma School of Medicine and University Hospitals, Oklahoma, CS-9351 (C2)	Dr Jean Spencer Felton	Incidence of occupational cancer in an industrial agricultural State with emphasis on the occurence within the petroleum industry.	16,170
University of Pennsylvania, Philadelphia, Pa., CS-9246 (C3).	Dr. Douglas P. Murphy	The occurence of cancer in the male members of families in which the incidence of cancer in the female members has been determined.	7,927
University of Pittsburgh, Pittsburgh, Pa., CS-9187 (C5)	Dr. A. G. Kammer, Dr. W. E. Poel	Identification of carcinogens in coal byproducts	37,893
University of Utah, Salt Lake City, Utah, CS-893 (C8)	Dr. Charles M. Woolf	Genetics of human cancer	10,174
Utah State Department of Health, Salt Lake City, CS-9499.	Mr. John W. Wright	Cancer mortality in a closed population, Utah State Department of Health, Mr. John Wright, Bureau of Vital Statistics.	6,912
Total (22 grants)			340,516

(NOTE.—Progress report, National Institutes of Health, entitled "External Agents in Cancer Causation," will be found on p. 293.)

Mr. WILLIAMS. I believe we have with us this morning, Dr. Ray. I do not have your initials, Doctor.

Dr. RAY. Francis E. Ray.

Mr. WILLIAMS. Doctor, we welcome you to the committee. We are sorry we will not have more time to accord you this morning, but the committee will listen with a great deal of interest to what you have to say.

Dr. RAY. Thank you, Mr. Chairman.

Mr. WILLIAMS. First, I think it might be well for you to identify yourself for the record.

STATEMENT OF DR. FRANCIS E. RAY, RESEARCH PROFESSOR AND DIRECTOR, CANCER RESEARCH LABORATORY, UNIVERSITY OF FLORIDA, GAINESVILLE, FLA.

Dr. RAY. I am Francis E. Ray, research professor and director of the cancer research laboratory at the University of Florida, in Gainesville, Fla.

My training has been along chemical lines, and my interest has been in the application of chemicals to the animal body, with particular interest in the production of cancer by chemicals.

There are just a few points I would like to make. The first is the difference between an ordinary toxic chemical or substance and a cancer-producing chemical.

The ordinary toxic-producing chemical, if used in small amounts, very small amounts, may not be harmful; or, if used in large amounts, it may cause illness from which the patient completely recovers. And those effects are rather quickly produced in a short period of time.

The cancer-producing chemicals may be applied in very small doses; we have used solutions of five ten-thousandths of 1 percent on mice, and 2 paintings on their backs at intervals of 3 and 4 months have produced tumors.

These substances that produce cancer take a long time to act. If we consider the life of a man to be about 30 times the life of a mouse, and it takes a year to produce chemical cancer in the mouse, that would be equivalent to about 30 years in a man. So there is no way that we can determine, on human beings, over any short period of time, whether a substance is going to produce cancer or not.

Some people have raised the question that a mouse is not a man, and just because you can produce cancer in a mouse with a chemical does not mean that the man will get it. There is a certain element of truth in that, but it is very misleading, because chemical cancer was first discovered in man, and then animals were tested with these same chemicals that we suspected of causing cancer in man, and it was found that the animals responded to chemical cancers as well as man.

I think the point to emphasize is that very small doses produce in the cell an irreversible change, and other small doses will push that change along into active cancer. The production of cancer by chemicals is considered to be divided into two stages—initiation and promotion—and certain chemicals will initiate changes in cells that will

Total (22 grants)

lie dormant for years, waiting for some promoting factor to push the dormant cancer cells into active cancer production. That, I think, is why House bill 7798 is so important. It takes up this matter of the possible production of cancer by food additives.

I wish to make one other point, too, and that is, our experiments show that the younger the animal is when he is treated with cancer, the more certain is the production of cancer. And so, we may be initiating cancer in the children of today by the addition of chemicals, and they are very susceptible to that. We will not know, perhaps, for a generation or two what the effects will be.

I was a member of the symposium which has been mentioned, which met in Rome last summer, and it seems that all over the world people are concerned with the problem that lies before you gentleman today. And they suggested that the tests should be run, not only on more than one species of animals, but that their offspring should also be studied for any possible genetic effects.

Those are the points I wished to make especially, Mr. Chairman.

Mr. WILLIAMS. Doctor, are there any known or proven carcinogens in use today as food additives?

Dr. RAY. I would not be prepared to say that there definitely was. Recently, some of the coal-tar colors have been withdrawn from the approved list because they were suspected.

Mr. WILLIAMS. Mr. Dies?

Mr. DIES. No questions.

Mr. WILLIAMS. Mr. Heselton?

Mr. HESELTON. Doctor, how long have you been with the University of Florida?

Dr. RAY. In 1949, I went to the University of Florida and established the cancer research laboratory. Before that time I was at the University of Cincinnati for 19 years, and was director of the laboratory of radiochemistry, in which we used radioactive substances to trace the course of cancer-producing chemicals in the body.

Mr. HESELTON. In that connection, you have been very active in the research into the causes of cancer, as I understand it.

Dr. RAY. Yes. We have published, I think, some 30 papers on chemicals that are of interest to cancer research.

Mr. HESELTON. You are familiar with other papers that have been published by other people engaged in research?

Dr. RAY. Fairly familiar.

Mr. HESELTON. Is it not a fact, Doctor, that the introduction of certain elements or substances into the muscle of test animals will produce malignant tumors if they are repeated, and in sufficient doses?

Dr. RAY. What kinds of substances do you refer to, sir?

Mr. HESELTON. Specifically, has it not been established that the introduction of nickel in powdered form into the muscle of a rat will produce a malignant tumor if it is in a sufficient amount and at frequent intervals?

Dr. RAY. That is correct.

Mr. HESELTON. Is it not also a fact that the introduction of a similar or somewhat similiar quantity of cobalt under the same circumstances will produce somewhat similar results?

Dr. RAY. I think that is correct.

Mr. HESELTON. Cobalt is found in certain quantities in a great many of the foods we are accustomed to eat, in fruits and vegetables; is that not true?

Dr. RAY. It may be found in very minute amounts.

Mr. WILLIAMS. Do you mean in their natural state?

Mr. HESELTON. In their natural state.

Dr. RAY. In certain sections of the country where there is heavily infested soil, that may be true.

Mr. HESELTON. Have there not been experiments made or research conducted with reference to the effect of the use, under similar circumstances, of certain fats and oils?

Dr. RAY. There have been certain experiments conducted by Peacock, in Scotland, of highly heated oils, food oils, that have produced papillomas in the gastrointestinal tract; and it is his contention that the oils, when highly heated, are converted into carcinogenic substances.

Mr. HESELTON. And there have been similar experiments conducted with reference to use of peanut oil, lard, olive oil, and cottonseed oil, and somewhat similar results have been observed by people engaged in research; is that not true?

Dr. RAY. Yes. There may be something to this business of highly heated oils producing carcinogens.

Mr. HESELTON. Going back to the question of the quantity of nickel that is found in foods in the natural state—nickel is found in that quantity in cabbage, lettuce, potatoes, peas, spinach, and wheat, among other foodstuffs; is that not true?

Dr. RAY. It may be found, if those elements are in the soil to a considerable concentration.

Mr. HESELTON. And cobalt is found in minute quantities in apricots, beans, beets, cabbage, carrots, corn, lettuce, pears, peas, spinach, and potatoes; is that not a fact?

Dr. RAY. It may be, if the soil is infested.

Mr. HESELTON. With that in mind, and as to the provisions of the bill you have endorsed, my colleague, Mr. Delaney's bill, H. R. 7798, do you suggest that the Administrator should have any discretion or any power with reference to the exclusion of any additive such as this which might produce cancer in animals, test animals, if it is in sufficient quantity and at such frequency?

Dr. RAY. Well, sir, my feeling is that there may be certain hazards in natural conditions, but that we should not permit additional hazards to be added to our food.

It is quite true that food grown on certain types of land does take up minerals that may be harmful to people. But that is no reason, it seems to me, sir, for adding those things deliberately to our food supply.

Mr. HESELTON. Well, the bill itself, of course, gives or lays down a standard that the Secretary shall not approve for use in food any chemical additive found to induce cancer in man or, and this is the particular language that I am interested in, "after test found can produce cancer in animals."

Now, the reason for my questions with reference to these experiments with reference to cobalt and nickel and fats and oils was to inquire of you whether or not it has not been established that the use

of those particular substances can produce cancer or malignant tumors in animals.

Dr. RAY. That is true.

Mr. HESELTON. One final question along that line: Is it not true that concentrated sugar, if introduced in a test animal in sufficient amount and at frequent intervals, will produce the same result?

Dr. RAY. There has been a report to that effect. But I would be extremely reluctant to accept that particular report that sugar injected into the animal will produce cancer. It needs a great deal more work before we could accept that, and I am very doubtful that it is valid.

Mr. HESELTON. My colleague has suggested one further question, because of the time element, and I will ask it:

Have there been any experiments made as to sugar concentrates or substitutes?

Dr. RAY. I do not quite get your question, sir.

Mr. HESELTON. Have there been similar experiments on animals by injection of sugar substitutes or concentrates, to your knowledge?

Dr. RAY. No; I do not know of any other.

Mr. HESELTON. Thank you, Doctor.

Mr. WILLIAMS. Mr. Rhodes?

Mr. RHODES. No questions.

Mr. WILLIAMS. Mr. Schenck, do you have any questions?

Mr. SCHENCK. Only to say, Mr. Chairman, I am happy to know Dr. Ray, of the University of Cincinnati, which is near my home city of Dayton, Ohio, and I know many of his associates there appreciate his statements here very, very much.

Mr. WILLIAMS. Is that all?

Mr. O'Brien?

Mr. O'BRIEN. Doctor, is there such a thing as a safe dose of a cancer-producing chemical?

Dr. RAY. There may be a safe dose of some cancer-producing chemicals, but we do know there is no safe dose of certain other cancer-producing chemicals. We do not know everything about cancer-producing chemicals. There, my feeling is we should be on the safe side. Because we know there is no safe minimum dose for certain cancer-producing chemicals, I think we ought to adopt that rule, at least tentatively, that there is no safe minimum dose, though I readily admit that there may be a safe minimum dose for some cancer-producing chemicals.

Mr. O'BRIEN. One more question, Doctor.

Suppose a chemical is found to induce cancer when tested by injection under the skin. Would it be prudent to use such a chemical in food? And should we rule out only chemicals that are shown to produce cancer when eaten, or should we rule out also chemicals which induce cancer by any route of administration?

Dr. RAY. I would be in favor of ruling out chemicals that produce cancer by any route of administration, and I might give you an illustration in this way: that stomach cancer is one of the most malignant forms of cancer in man, and yet animals are very resistant to either spontaneous stomach cancer or to chemically induced stomach cancer.

You can feed great quantities of known carcinogens to animals, and while they may get tumors almost everywhere else in their body, they do not get the malignant type of adenocarcinoma of the stomach that man gets.

So you see, you have no way of testing for gastric cancer, so far as we know. There may be some animals that are susceptible. But I have combed the files looking for authentic cases of adenocarcinoma of the stomach of animals, and I have only found 4 or 5, and they look fairly doubtful.

Mr. O'BRIEN. Thank you, Doctor.

That is all, Mr. Chairman.

Mr. WILLIAMS. Dr. Neal?

Mr. NEAL. Thank you, Mr. Chairman.

I am glad to know Dr. Ray is a former associate of the University of Cincinnati. I graduated from there back in 1906, at which time we knew very little about cancer, and I appreciate the wonderful improvement that has been going on in relation at least to the detection of cancer.

If we had a little more time, I would like to explore a situation which I think enters into this picture, but since our time is up, I will only bring just quickly to your attention this thing.

It is generally recognized that in most every human being, resulting perhaps from some accident that happened in embryo, that there are certain cells deposited outside of their habitat, and that they are potentially cancer cells.

I wondered, when you mentioned the question, whether the outside chemical usually confines itself to the stimulation of this particular cell that is out of place, and activates it, in time.

I would just like to talk that over with you sometime, and there is not quite time enough to bring it out in our discussion at this time.

Thank you, sir.

Dr. RAY. We have published a paper on ectopic cells.

Mr. SCHENCK. Mr. Chairman, could I just ask one brief question?

Did I understand you, Dr. Ray, to say these are irreversible reactions?

Dr. RAY. Yes. The difference between toxicity of ordinary poisons and cancer-producing chemicals is that the ordinary toxicity is reversible, but the cancer type of chemical produces an irreversible change.

Mr. SCHENCK. Are you now studying the possibility of developing something else that will reverse this situation?

Dr. RAY. It may be possible to do that.

Mr. SCHENCK. Thank you.

Mr. WILLIAMS. Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

Doctor, will you tell me whether you have any familiarity with this betanaphthylamine?

Dr. RAY. Yes. I have talked to and with Dr. Bonser, of England, who did the original work in that field, and they had something over a hundred well-authenticated cases in the dye industry in Great Britain that were studied there, that were undoubtedly——

Mr. DINGELL. Induced by working with this chemical?

Dr. RAY. Working with this chemical in the dyeworks.

Mr. DINGELL. Let me ask you this: Do you have any familiarity with the chemical descendants of this, derivatives of this substance?

Dr. RAY. It is a very useful chemical, because it couples with other chemicals to produce what is known as the azo dyes, a very brilliant dye, series of dyes, in a wide range of colors there, and as suggested by the previous speaker, those dyes are often decomposed in the animal body, and we have made some of these compounds radioactive, and we find that they lose their color, showing they have been reduced and split, and we think that they probably go back to the original material there or some derivative of the original material which may continue to be carcinogenic.

Mr. DINGELL. Do you have any evidence that any of these azo dyes, or reduced or oxidized azo dyes, have cancer-producing properties?

Dr. RAY. Yes. A number of azo dyes have been tested and have been found to produce cancer.

Mr. DINGELL. Would you be able to submit to us a list of those azo dyes which do produce cancer, and any which happen to be used as food additives, to your knowledge?

Dr. RAY. I could not on the spur of the moment, because some of them have been withdrawn recently from the list of approved dyes.

Mr. DINGELL. Could you, at your convenience, perhaps be able to submit to us such a list?

Dr. RAY. I would be glad to, sir.

Mr. DINGELL. Have there been any tests on these azo dyes conducted to ascertain whether they produce cancer when inserted under the skin?

Dr. RAY. Yes; we have produced tumors by, not necessarily under the skin, but by painting them on the skin and by injecting them into the peritoneal cavity of the animal.

Mr. DINGELL. Doctor, I want to be very brief on this last question, because it runs over the amount of time I think I have, but tell me this, Doctor: What is the relationship between, let us say, painting these substances on the skin and causing cancer by using them as food, and what is the relationship between inserting these chemicals or substances under the skin and using them as a food? I mean, with particular emphasis on the possibility of these substances producing cancer in human being as food additives.

Dr. RAY. Yes; the mode of application is often of considerable importance, because, as I pointed out, various animal organs are more or less resistant, and so we generally try every means of administration before we have decided the compound is not carcinogenic.

Mr. DINGELL. Now, this point I want to get: Is there a good relationship between, or, rather, would it be good proof to show that a substance is a cancer-producing agent by painting it on the skin? Would that be good proof?

Dr. RAY. Yes; if you produce tumors, it is good proof. If you do not produce tumors, it is not good proof.

Mr. DINGELL. Then inserting these same substances under the skin or injecting them under the skin, would that be good proof, as good proof as painting them on the skin, of perhaps not so good proof?

Dr. RAY. There is room for difference of opinion there as to whether the subcutaneous route is effective. My own feeling is that if you can

show that by any route of administration the compound produces cancer, it is very highly suspect, and unless there was some extraordinary good reason for it, such as, say, the preservation of food for an armed expedition or something very vital of that kind, I would not be in favor of it.

Mr. DINGELL. Then this question occurs to me, Doctor: Would it be fair to say this, that you have, because of the difficulty of observing cancer and cancer-producing agents in the human body, that you have to perhaps apply a greater degree of safety and a greater degree of care and a greater amount of care on behalf of people in evaluating the results of your chemical and scientific investigations, particularly in regard to carcinogens? Am I correct in that?

Dr. RAY. That is correct, sir.

Mr. DINGELL. Thank you.

I would like to ask more questions, but I am going to have to yield back my time, and I thank the chair.

Mr. WILLIAMS. Mr. Loser, did you have any questions?

Mr. Dollinger?

Mr. DOLLINGER. Doctor, when a chemical is used as a food additive, is it determined before such use whether it is cancer producing?

Dr. RAY. It has not, up to the present time.

Mr. DOLLINGER. When is it ascertained whether it is cancer producing? After it has been in use for quite a while, or any length of time?

Dr. RAY. Well, it all depends on somebody getting interested in it and starting——

Mr. DOLLINGER. Who makes the tests?

Dr. RAY (continuing). And starting an investigation.

Mr. DOLLINGER. Who makes the test? Does the company using that make the test at any time, or is it made by an interested agency?

Dr. RAY. Very, very few companies have carried out tests for cancer. The usual tests are acute toxicity tests, and that is why I tried to explain the difference between acute toxicity and cancer-producing activity.

The usual tests that are carried out have been entirely toxicity tests over short periods of time, to see if there is any active effect there.

Mr. DOLLINGER. Is there any agency of Government that is required to make tests of any sort?

Dr. RAY. Yes. The Food and Drug Administration makes tests on most things, and I understand now they are adding cancer tests to their list. But, unfortunately, their funds have been too limited by the Congress to carry out an extensive program.

Mr. DOLLINGER. One more question.

Do they make those tests before the thing is put out for public sale?

Dr. RAY. They cannot do that at the present time.

Mr. DOLLINGER. That is all. I am sorry, my time has run out.

Mr. WILLIAMS. Dr. Ray, I am sorry the bell has foreclosed us. The House is in session. There is a call of the House, and the committee will necessarily have to adjourn.

But permit me to say to both you and Dr. Smith that we regret very much that the 11 o'clock meeting of the House this morning made it necessary for us to cut down on the testimony that was to be received.

It took an hour away from the committee, and we are sorry we did not have an opportunity to question you and Dr. Smith further.

But on behalf of the committee, I should like to express our appreciation to you for coming and giving what I am sure will be valuable testimony to the committee.

Dr. RAY. Thank you, sir. It has been a privilege to testify.

Mr. WILLIAMS. Dr. Hueper was scheduled to appear this morning. Obviously we will not be able to hear him. But I feel sure that we will be able to reschedule him for a later date which will be convenient for Dr. Hueper, I hope.

The committee will stand in adjournment until 10 o'clock Monday morning.

(Whereupon, at 11: 15 a. m., the subcommittee adjourned, to reconvene at 10 a. m., Monday, July 22, 1957.)

FOOD ADDITIVES

MONDAY, JULY 22, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334, New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. The committee will please be in order.

This morning the committee continues its hearings on the subject of food-additive legislation, and we are happy to welcome before the committee Mr. H. T. Austern, appearing in behalf of the National Canners Association.

I may state at this time that Judge John Biggs, chief judge of the third judicial circuit, is expected to arrive here around 11 o'clock. Because he is coming especially to testify before the committee this morning, it may be necessary to interrupt your testimony, Mr. Austern, in order to permit Judge Biggs to testify.

I understand you are here in Washington, and you would be available later, if necessary.

Mr. AUSTERN. As a lawyer, sir, I always yield to a judge.

Mr. WILLIAMS. I do, too.

Proceed, Mr. Austern.

STATEMENT OF H. T. AUSTERN IN BEHALF OF THE NATIONAL CANNERS ASSOCIATION, WASHINGTON, D. C.

Mr. AUSTERN. Mr. Chairman, the National Canners Association is described and its interest in this legislation is indicated in my statement and, if you will permit it, sir, if the statement could be included in the record, I might begin talking directly to the bills.

Mr. WILLIAMS. Yes, sir. If there is no objection, the statement will be inserted in the record.

(Mr. Austern's prepared statement is as follows:)

STATEMENT OF H. T. AUSTERN, APPEARING IN BEHALF OF THE NATIONAL CANNERS ASSOCIATION, WASHINGTON, D. C.

My name is H. T. Austern, and I am appearing on behalf of the National Canners Association, which is a trade association of approximately 800 canners, operating country wide in some 44 States and each of the Territories, and accounting for approximately 85 percent of the Nation's production of canned fruits, vegetables, fish, and canned food specialties.

As the directors of our two research laboratories told the Delaney committee in 1951, the problem of untested and possibly toxic chemical additives is not a major or acute problem with canned foods.

That situation exists for three reasons:

In the first place, for the bulk of canned foods, the canning process consists essentially of processing what is harvested at the peak of perfection, its immediate sterilization by heat, and the addition only of common salt or sugar.

Secondly, almost all of the conventional canned fruits and vegetables are now standardized, and their ingredients have already been administratively scrutinized as to wholesomeness.

Thirdly, the pesticide residue problem is now under control on the raw materials side under the 1954 Miller Pesticide Act.

But the canning industry is vitally concerned with this legislation for a number of important reasons.

First, we have an important interest in the occasional suggestions that antibiotics might be used in processed foods; and we have a considerable interest—and are doing massive research—in the suggested use of radiation from nuclear fission sources as a means of preserving food.

Second, with constant research and product development, many fabricated, ready-to-eat foods are being canned, and in their development the use of new ingredients is not unlikely.

Finally, the National Canners Association owes its basic origin and a large part of its growth to Federal food and drug legislation. The association was organized in 1907 at the time of the first act. During its 5 decades of existence its research laboratories have regularly worked in cooperation with those of the FDA.

The association has constantly sponsored and supported new food and drug legislation and amendments. It sponsored the McNary-Mapes amendment of 1930 which was the grandfather of food standards. It played a very considerable part in the development of the 1938 act which is today's basic statute. The association has also actively supported subsequent amendments, including the Miller amendment, affording Federal control after interstate shipment, the factory inspection amendment, and the two Hale amendments.

No industry has worked more closely with the FDA in the development of food standards. The bulk of all existing standards cover, as I have already suggested, canned foods and fish.

In short, the canning industry is among the more important industries regulated by the FDA. Necessarily, it is interested in any basic amendments to the law. It is cardinally concerned with any amendments which might change the entire structure of regulation, the basic relations between the FDA and those who desire voluntarily to comply with the law, and with any new legislative structure that many affect the development of new and better processed foods for the American housewife.

The canning industry supports the basic principle of pretesting of every new food ingredient so as to insure its wholesomeness and safety for the intended use.

The canning industry unqualifiedly supports H. R. 8390, the Harris bill, and H. R. 8629, the Wolverton bill. The canning industry opposes, not the underlying purpose but the basic licensing scheme of H. R. 6747, the FDA proposal.

With your permission, it is my purpose this morning to attempt to crystallize the bases for that position. Perhaps it will be useful to the committee for me to endeavor to do so from three points of view.

In the first place, may I point out, in nonlegal terms, the practical differences between the two proposals. In doing that, I hope that I can crystallize for you the areas of basic agreement, and the far smaller areas of disagreement. While these areas of controversy are narrow, they are unfortunately sharp and in our view vital to the food industry as a whole.

Secondly, with that background before you, perhaps I can discuss in detail the six key questions which this committee must resolve on these bills. I hope to persuade you that these are fairly and effectively resolved in H. R. 8390.

I hope to do that because for the past several years this committee has been considering these proposals to provide additional control over the use of new food additives whose toxicity, or potentiality to injure the public health, has not been adequately determined. Last year the committee held hearings on some eight bills. H. R. 8390 represents an effort to deal with the differences that were developed in those hearings. H. R. 8390 is in no sense a canning-industry

bill. It contains many ideas objectively distilled from what was requested last year by the FDA, what was urged by food industry representatives, and what was said by members of this committee at the hearings.

For the paradox is that everyone is in agreement as to the need for legislation. No one disagrees with the proposition that any new food additive, whose possible toxicity is unknown, should not be employed without adequate pretesting as to its safety. No one disagrees that the information concerning that pretesting and safety should be presented to the Food and Drug Administration for its consideration in advance of any use of the new ingredient in any food.

I might add that by and large that has always been the canning industry practice.

Since I am also atempting to present a full picture, I should add that there are some people in the food and chemical industries who honestly believe that the entire problem of new additives has been exaggerated, and that the provisions of the present law are fully adequate; but those holding this view appear to be in the minority.

As my final objective—after dealing with the basic areas of controversy—I hope to offer for your consideration certain technical legal modifications that appear to be desirable in the language of each of these bills.

Turning to the first task, and completely avoiding legal technicalities, may I endeavor to demonstrate in practical terms how each of these bills would operate.

Let us suppose that the Jones Food Co. discovers that by adding a minute quantity of a new ingredient to its product, it can make the product better. The new ingredient might improve its appearance; or it might make the product taste better, or act more smoothly when used in cooking; or it might facilitate its production so that it could be made more cheaply.

This new ingredient might be a chemical, or it might be derived from a vegetable or even a seaweed. The point is that it is a new food ingredient. Although some of these bills are titled as "chemical additive" proposals, every one of them covers every new food ingredient—animal, vegetable, chemical, biological, natural, or even something not found in nature that might be developed by irradiating some common food.

Even recognizing that the words "chemicals" and "chemical additives" are politically attractive, the committee must be realistic and acknowledge that it is dealing with all new food additives.

The first job of the Jones Co. is to determine whether the new ingredient it wishes to use is "generally recognized" by qualified people as safe in the quantities and under the conditions of the intended use. Its own research people, or some outside consultants, would examine the scientific literature and might find that nothing is known one way or the other about its safety. If there was any doubt, the Jones Co. would informally ask the FDA. Let us assume that it is determined that there is no basis for saying that the new ingredient is generally recognized as safe.

The Jones Co. would then be obligated to pretest the new ingredient before using it. This is done by testing it on animals. Obviously, you cannot use human beings as guinea pigs. The ingredient is first tested for acute toxicity, that is, to determine whether at the levels being considered, it would have immediate pathological effect. That is only the beginning point. The new ingredient must also be tested for chronic toxicity to determine its possible effects when taken over a long period of time. Necessarily, also, in this determination one must consider how much of the same or a related substance might be derived from other foods in the diet and whether the new ingredient might react with other substances in the diet to produce adverse effects.

The research work done on animals must then be extrapolated to man. There are scientific techniques for doing so and in each of them safety factors running as high as 100 to 1 are employed.

It is usually at this point that scientific toxicological and medical judgment—and often some plain commonsense—must be called into play. What are we trying to measure in determining that an ingredient is safe for the intended use? What must the Jones Co. in its pretesting be ready to establish, under H. R. 6747, that the new ingredient in its intended use is "without hazard to man"?

The Jones Co.—and this committee—hears talk about substances that are "poisonous or deleterious." You will hear talk about a per se rule in the existing law. This prohibits "any poisonous or deleterious substance that may render (the food) injurious to health." That language has been judicially interpreted to mean any substance that has a tendency to "destroy the vitality of the human body."

But the scientists will tell the Jones Co. that the concept of safety is always relative, and depends upon the character of the new ingredient and how much of it one takes and what happens to it in the body.

As Mr. Coleman suggested to the committee, common salt in large enough quantities is poisonous. There are many foods which, if eaten exclusively, would soon kill a human being. There are many diets of conventional foods which, if taken over a long time, would cause serious disease. Indeed, it was suggested that one could commit suicide by drinking enough ordinary water.

Back in 1950 Dr. Koppanyi told the Delaney committee that from this point of view—and getting away from new food ingredients—there might be a large number of staple food articles which are now considered completely innocuous that might not pass in extensive testing of their longtime effects. Still, if after pretesting the experts cannot say that a proposed new ingredient is absolutely safe, even if you ate a ton of it, they can come up with a realistic and workable appraisal of safety at a given level of use. Of course, in that evaluation the pretesting experts—and the FDA— must be conservative. They must play it safe, and not take chances with the public health. That is why these toxicity-testing methods have and should have wide margins of safety.

As Mr. Goodrich, the counsel for the FDA, said in New York last week: "Our methods do give us an assurance of safety which removes all reasonable doubts." This is true even though, in his words, "there remains a gap between reasonable doubt and absolute certainty which science cannot cross."

I might add that this involves somewhat the same kind of a doubt that exists in the present arguments about the effect on heart disease of eating butter; or about a diet that is composed exclusively of vegetables or of meats, or the drinking of certain types of mineral water.

But suppose the Jones Co., after spending a large amount of money and a long time, is told by reliable toxicologists that its new ingredient is safe. Suppose that it is told enough to satisfy either what H. R. 6747 prescribes as being "without hazard to the health of man," or what H. R. 8390 says in simpler and clearer language, "safe for use under the conditions of its intended use." Let us see what happens to the Jones Co. under each of these bills.

Under the FDA bill, the Jones Co. files a petition with the FDA which sets forth all the information as to safety. In addition, and very important, the Jones Co. must also set forth why it thinks using this supposedly safe ingredient will improve the product, or lead the consumer to prefer it, or help in its manufacture. This is called, in the FDA bill, the data bearing on the functional value of such additive.

But on that point, the Jones Co. is stymied. Under neither bill can you market a food containing the new ingredient until the pretesting data has been checked by the FDA. You cannot determine consumer reactions if you cannot ship the product. You cannot verify production economies until you manufacture commercial quantities. So in this part of its application the Jones Co. is more or less limited to a flat statement of "functional value"—and the FDA completely free to make its own determination.

Once the application is filed—with the pretesting information—and something necessarily untested on "functional value," under H. R. 6747, the Jones Co. then waits 90 days. If within the 90 days the FDA wants more time, this initial waiting period can be extended to 180 days. Within that 6-month period the FDA reviews the safety data. By FDA I mean the entire group of people in that agency. The FDA decides two things: The first is whether the ingredient in its intended use is safe. The second is whether, in the FDA's opinion, it really has functional value, that is, the FDA decides whether it will be useful to the consumer in improving the product, or in making it more convenient for the consumer's use, or improving its processing, storage, or handling.

How it determines functional value is wide open. There is no definition or standard in H. R. 6747.

At the end of 180 days FDA issues an order. The order either licenses the use of the ingredient in whatever way the FDA decides it may be used for a particular food, or the FDA denies the application and refuses to license the use of the ingredient. When the Jones Co. gets an order denying its application, it can within the next 30 days ask that the question be referred to what is called an advisory committee. This is composed of experts designated by the National Academy of Sciences, or if they can't be found to serve, the advisory committee is selected by the FDA.

Of course, the Jones Co. can go around and lobby with each of the men on the advisory committee. The FDA proposal gives the company the right to consult with the committeemen, but it doesn't tell how they do it, or when, or where, or what happens if the advisory committeemen, refuse to talk with the Jones Co. experts. In any event, after another 3 months, if there is a reference to the advisory committee either by the Secretary or the Jones Co., the advisory committee files a report and its recommendations.

I might mention that before Jones Co. can use the advisory committee it may have to put up fees to pay for the committee's expenses.

When the FDA gets the advisory committee's report, H. R. 6747 provides for another month to consider it, and then the FDA either modifies the original order or issues it as first promulgated. The next thing that the Jones Co. can do, if it is still turned down, is within a further 30-day period to file its objections and to ask for public hearing.

The Jones Co. then waits some further time for the hearing to take place—which H. R. 6747 doesn't specify but which can be fairly long, because the FDA can delay as long as it desires in scheduling the hearing. At the hearing the Jones Co. can present its experts, and the FDA presents its own. In addition, the report and recommendations of the advisory committee are also thrown into the record.

Of course, at this administrative hearing in the FDA there is no judge. Instead, there is a lawyer from the FDA who presides. I don't think I would change my description last year of that hearing officer as a recording instrument that merely maintains order. He decides nothing.

The record is then considered by the FDA, once again by everybody in the agency, including the FDA witnesses who appeared and gave the objecting testimony. After a further long time, since once again H. R. 6747 specifies no period, the FDA people get up a series of administrative findings and conclusions. Even if they then conclude that the Jones Co. can be licensed to use the new ingredient, that license does not take effect for another 90 days.

But let us assume that the Jones Co. is still turned down. Let us assume further that it feels that the FDA refusal is unwarranted and that the careful pretesting it did warrants the licensing of the new food ingredient both because it is safe, and also because, despite the FDA views, it serves a useful purpose. This brings us to the court review area.

Of course, if the Jones Co. wants to go to court it risks serious adverse publicity. If the Jones Co. has competent counsel, it probably also will be told several other things.

The first is that the FDA's determination as to whether the ingredient has functional value is just as controlling under H. R. 6747 as its determination on safety. Obviously, the question whether an ingredient is functionally useful is hardly a medical judgment, but in any court presentation the issues as to safety and functional value will be pretty well mixed up. The Jones Co. will also be told that if the advisory committee report was against it—even though there are no full records as to what either the company or the FDA said to the gentlemen on the advisory committee privately, publicly, or in any other fashion—that fact alone will be a big stumbling block to any successful court review.

But most important, the Jones Co. will have to appreciate that under H. R. 6747 the reviewing court will never see any witnesses, will have only a paper record, and that the working rule will be that if on the whole record there is any evidence to support the findings made by the FDA, the appeal will not succeed.

Realistically, the Jones Co. will have to appreciate that, no matter what form of judicial review prevails, it will have the proverbial chance of a snowball in getting any judge or group of judges to overrule the FDA when it is backed by the whole paraphernalia of an administrative record, findings, and conclusions.

Under the new drug section of the law, over 19 years there were 11,000 new drug applications, and in the only case in which there was an appeal to a district court, the judge affirmed the FDA without hearing from Government counsel.

Let us look now at what the Jones Co. would do under H. R. 8390: It would have to make the same initial determinations or inquiry of the FDA as to whether its new ingredient was generally recognized as safe for the intended use. It would have to do the same scientific pretesting as to acute and chronic toxicity. It would have to file all of the same information with the FDA—except that the unavailable information proving that the ingredient would be useful to the consumers or useful in production would not be called for. The only question would be whether the ingredient was safe for the intended use.

As under the FDA proposal, the Jones Co. could not, under H. R. 8390, use the new ingredient unless and until it had pretested the new ingredient and had submitted its data to the FDA. The FDA would get 120 days to examine the information unless, in the course of administrative discussions, it was agreed by the Jones Co. to extend the time. In almost all cases, where more time was needed, the Jones Co. would, of course, agree to the extension.

The FDA would examine safety. It could do so broadly and comprehensively. It would then notify the Jones Co. by registered mail that the new ingredient had been pretested enough and that it was safe, or that it was not and indicate why the FDA thought so. In addition, the FDA might publish a notice that it had concluded that the proposed use was not safe, and thereby put everybody else on notice of its position.

If it were turned down, the Jones Co. could not begin to use the new ingredient even if it thought it was right. If it wanted to do so, it would have to give the FDA at least 3 months' additional notice of its proposal to ship the ingredient or any food containing the ingredient, and would have to tell the FDA how much and where and to whom the shipment was going.

If the FDA wanted to keep the new food ingredient off the market, the FDA could then go to the district court and get a restraining order. Of course, that would stop the Jones Co. from using the new food ingredient, but it could then have real judicial review within a reasonable time.

But even under H. R. 8390, the Jones Co. would have to understand that the chances of getting the Federal courts to second guess the FDA on the question whether a proposed ingredient was safe were as remote as the most distant star.

Reversing the FDA under H. R. 8390 would be far more difficult because the only issue involved would be that of safety to the public health. The Jones Co. would know that only if it could demonstrate, completely and persuasively, that there were no doubts about safety and that there had been a plain abuse of administrative discretion could it possibly prevail.

Even though under H. R. 8390 the Jones Co. could get a real judicial trial, and could cross examine the FDA experts before a trained judge, its chances of successfully overturning the FDA position that its new ingredient was a hazard to the health of man would be about one in a hundred thousand.

Finally, the Jones Co. would have to be told that, even if the FDA could not make its restraining order stick in the first instance, it would always remain free on additional information to seize the goods, to bring a new injunction action, or even to prosecute the company criminally.

Thus, whatever comfort the Jones Co. might take from the absence of any hocus-pocus about advisory committees or from the opportunity to get the judicial review decided within something less than 2 years, the practical result would be that, unless it could administratively satisfy the FDA that its ingredient was safe, it would be still civilly and criminally prohibited from using it without that clearance.

For the public, the result under H. R. 8390 would be the same. No new food additive could be used until it had been pretested and until it had been determined that it was safe. Probably more important for the public would be that the question of what was useful or desirable in the diet would be left for the consumer to determine, and not blocked by a licensing system buried in the administrative machinery of determining functional value along with safety.

For those interested in maintaining the fundamental concepts of free enterprise, the difference between responsibility with effective control and the deadening effect of licensing would be regarded as well worth preserving.

So much for the way the two proposals would operate.

May I turn now to the specific issues, the arguments about each of them, and how they might be resolved.

They are six in number.

1. The controlling definition to be employed.
2. The so called grandfather clause.
3. The argument about "functional value."
4. The issue of licensing versus direct enforcement by the FDA.
5. What is the proper reviewing court.
6. Whether the advisory committee complication is necessary and useful.

1. As to the definition, we think there is no escape from using the admittedly vague standard of "generally recognized" by qualified experts. But we suggest there is really very little worry on this point. As the new drug section experience suggests, unless the one using the ingredient is absolutely certain, the

risk of criminal penalties will result in his asking the FDA whether it thinks a new ingredient falls within the act or is generally recognized as safe.

There appear to be two differences between H. R. 6747 and H. R. 8390 in the definition. H. R. 8390 (p. 2, lines 3–5) says that an ingredient is covered if it "becomes or could reasonably be expected to become" either a component of the food or to affect its characteristics. H. R. 6747 has much more involved language about "directly or indirectly" resulting in the ingredient becoming a component or affecting the food's chartceristics (p. 2, lines 1–8). The difference may be between adding an ingredient deliberately and its accidental incorporation.

The controls sought by this bill relate to what is deliberately and intentionally added to a food or which ordinarily can be expected to get into it. They are not intended to cover accidents.

The second difference between the definitions is that the FDA proposal attempts to spell out what is a qualilfied expert, whereas H. R. 8390 simply specifies that they must be qualified and experienced in evaluating the safety of food. The second one seems better because the additional language "toxicity or other potentiality for harm" confuses the idea of "safe for use."

2. As to the grandfather clause, the principal change in H. R. 8390 is the inclusion of the words "formal or informal," and "shown to have been" on page 2, lines 15 and 16. The purpose of this change is simple to state. Over the past 19 years many manufacturers have in good faith gone to the FDA and inquired about the propriety of using a particular ingredient. They have often been told informally that such use was proper and have not bothered to get a formal letter. We believe that if anyone can demonstrate that he got informal approval from the FDA or the Meat Inspection Division, he ought not to be required to go through the new procedures. Under H. R. 8390 the burden is on him to demonstrate that fact, subject to criminal penalties if he cannot.

3. There is little to add to the discussion of "functional value. The industry I represent is adamantly opposed to having any Federal agency determine what the American consumer likes or dislikes or what serves a useful purpose in a food.

It is no answer to say that something of this sort is done when food standards are developed. Food standards involve entirely different considerations; there are experimental permit procedures to permit flexibility which are not applicable here; and indeed at the moment there is a vast argument about the coverage of food standards.

I would like to add one point about H. R. 6747 on this issue of "functional value." In the section relating to advisory committees, it is provided that this floating advisory committee can have referred to it "any question of fact" that is raised. Page 10, line 13: It is bad enough to have a Federal bureau determine what is or is not attractive or useful for a consumer in a food. It is compounded heresy to enact a law which permits this question to be loosely referred to a committee of scientists.

As I have suggested, the determination of functional value is hardly scientific. It is probably esthetic and inescapably economic. It ought to be answered on the grocery shelf or by the consumer in the kitchen, and not by either a Federal bureau or a learned society.

By the same token, the language on page 8, lines 15 to 18, of H. R. 6747, proves too much. These words say in effect that if a new ingredient is perfectly safe, functional value shall not be considered. The whole point of this bill is to determine what is safe and what is not safe within reasonable and workable limits. We appreciate that the FDA must and will be conservative in determining safety. But once it has determined that for a particular use an ingredient is without hazard to the health of man that should be the end of the matter.

4. The basic question as to whether there should be a licensing system or whether the pretesting, filing of data, and immediate automatic injunction provisions of H. R. 8390 should be employed has already been argued to this committee.

It must be clearly understood that H. R. 8390 does not take away any enforcement weapon that now exists. It does not weaken or impair the FDA power to seize, to enjoin, or to prosecute criminally.

What it does do is to create a new criminal and civil prohibition against using any unknown new ingredient without pretesting to determine safety and without giving the FDA 3 months—and more by agreement—to examine that pretesting work. If the FDA is not satisfied, the ingredient still cannot be used

for 3 months, and if a court test is wanted, the FDA is given the basis for a restraining order that prevents use until the court review is finished.

The public is protected without a complicated licensing system, and without elaborate administrative mumbo jumbo.

The trouble may be that people use false analogies. The new drug sections are wholly different. Indeed, as they are administered, they are more like patent provisions than regulations. If one manufacturer establishes in a new drug application that the new drug is safe, presents abundant clinical work to prove it, another manufacturer cannot get an identical product approved unless he repeats the same clinical work. It seems to us that this analogy to the new drug section created only confusion. Moreover, if you use an analogy, you ought to take all of it. The court review in the new drug section lies in the district court and not in the court of appeals.

There is also no point in making a long speech about the basic orientation of our laws toward freedom of activity and not prior Government approval. If the committee is interested in the complete historical and legal background, I have given to the staff a long paper presented some years ago to the Institute of Food Technologists.

But what is simple and vital is to understand that the canning industry—and so far as I know, most important groups in the food industry—is unwilling to accept a system whereby what it may pack, how it may improve its products by adding new ingredients, and how it may operate are to be subjected to Federal licensing control. Only where the paramount public interest cannot otherwise be protected will the objections to that proposal be waived.

In this instance, H. R. 8390 affords abundant public protection. In the one case in thousands in which a manufacturer, who believes that his pretesting has adequately established safety and that the FDA has acted arbitrarily, will risk the publicity and invite a judicial test, he must give to the FDA at least 3 months' notice and furnish a complete basis for an immediate restraining order. This will effectively stop the use of any ingredient which the FDA feels is not safe.

In informal discussion, the question has been raised as to the status of some other manufacturer, acting independently of the applicant whom I have called the Jones Co., and the possibility that this other manufacturer would not be prohibited from using an unapproved new ingredient or know about one that was approved.

This suggestion has led to a further provision that probably ought to be included in H. R. 8390. It ought to be included not only to meet the theoretical objection advanced, but also to avoid one of the difficulties under the new drug act that I have already mentioned. There ought to be inserted after subsection (d), on page 6, line 13, of H. R. 8390, a provision reading:

"Whenever the Secretary notifies any person who has submitted pretesting data on any new food additive that, in his opinion, such additive has been adequately pretested and is safe for the conditions of its intended use, he shall forthwith publish in the Federal Register an announcement of the ingredient and the conditions of its use that have been so approved."

A comparable addition should be made to subsection (3) at line 18 so as to provide that, if the Secretary ever withdraws his approval, a similar notice ought to be published in the Federal Register.

The effect of this addition will be that if any ingredient is approved for one company, it will be open to use by all others. The pretesting and the clinical work, which is costly and time consuming, will not have to be unnecessarily duplicated.

If the use of the new ingredient is subject to protection under the patent laws, the company which develops it can take advantage of those laws. It is not the function of any food and drug controls to establish supplementary protection to the patent system. Once this addition is provided, all theoretical difficulties with subsection (g), the injunction provision, will disappear.

If the ingredient has been approved by the FDA, the applicant and everyone else will be free to use it. If it has not been approved, no one else will be permitted by law to utilize the new ingredient unless he has pretested it and filed his data in accordance with H. R. 8390. That is the basic prohibition of the bill.

That disposes of the objection that a restraining order and injunction against one man does not bind everyone else. For everyone else is criminally prohibited from using the ingredient, and in this respect H. R. 8390 is identical with H. R. 6747. The criminal penalties apply to the same prohibited conduct.

Some may further be concerned that subsection (g), page 7, line 5, of H. R. 8390, leaves it to the discretion of the Federal court as to whether a restraining order should be issued. That objection is wholly unrealistic to those experienced in this field. In the one case in thousands in which this injunction provision will come into play, because a manufacturer deliberately seeks a court test, there can be little doubt that a United States district court will issue a restraining order on the FDA representation that the ingredient is not safe for its intended use. Obviously, the threatened public inquiry requirement is built into H. R. 8390 provision that the FDA be given 90 days' notice of the shipment.

Yet, if the committee decides to button up this point, it can very simply do so by including at the end of the first sentence in subsection (g), on page 7, line 11, the following:

"If any injunction proceeding is instituted with respect to such additive or any food bearing or containing it, it shall be a violation of section 301 to ship such additive or such food unless and until the injunction suit is finally determined in favor of the defendant."

The same result can be achieved by adding this provision as a separate paragraph in section 301.

In either event, the institution of the injunction suit would completely foreclose shipment by the defendant. And, of course, everybody else is basically prohibited by the bill from using the ingredient without following the prescribed procedure from the beginning.

For technical symmetry, the word "also" might be included before the word "issue," in line 12, so as to make it clear that, in addition to the criminal penalties provided in section 303, the use of the ingredient before the court decides the case would likewise be contempt of court.

5. As to what should be the reviewing court, there is obviously a threshold question. Why, if successfully overturning the FDA in court is so remote and hopeless a task, should anyone care as to whether they get judicial review before a judge who sees the witnesses instead of merely on paper findings in a court of appeals? The answers are real and important.

In the first place, it is largely because anyone who challenges the FDA on an issue of safety has almost an impossible assignment—principally because, as I suggested last year, the FDA has such momentum in sustaining its position before any tribunal—that a real trial with live witnesses heard and seen by a judge is essential. As Judge Biggs told the committee last year, court of appeals review is on the findings of the agency and the entire supporting record. Questions of fact are not reviewed except on the whole record.

But these findings are agency findings; they are prepared by the FDA staff. It is only natural that they are formulated, stated, and prepared strongly to support the agency position. There is no opportunity to examine or cross-examine any witnesses before the court of appeals.

Let us look at the point specifically as it is written in H. R. 6747. The findings of the agency are prepared after the agency holds its own hearing before its own lawyer as a presiding officer. The judicial review operation is a paper operation done on a vast record. The arguments in the court of appeals must be directed to the findings, and not directly in terms of the particular issue on which the petitioner wants attention focused. In the event of arbitrary or capricious action, the findings insulate the actors from live, judicial scrutiny.

The second—and indeed the essential—reason for review in the district court derives not from what may happen in court in a particular case but from the salutary effect of real court review on agency action. I have often urged that the real reason for any hearing is to expose administrative action to cross-examination. He who regulates—he who determines not to accept scientific evidence—ought to be made to appear and answer why. If those who make administrative decisions know that where they act arbitrarily they may be interrogated before a trained judge, the indirect effect on careful action in the agency is fully felt even though realistically the reviewing judge will almost never overrule the basic agency decision.

This salutary effect within the agency cannot be achieved where they know that they are insulated by the administrative finding process and that they can never be subjected to disciplined courtroom inquiry before a live judge.

So far as I know there have been only three objections to having these infrequent court reviews in the district court, as is indeed now provided in the new drug section of the existing law.

The first is that the lower courts will be burdened. With all due deference, this is nonsense. As I reported, under the new drug provisions there has been but one court review unsuccessfully sought in over 11,000 applications. The objection of burdening the courts is essentially a bugaboo.

The next objection is that the lower Federal courts are somehow incompetent to decide scientific questions of fact. There are many answers to this supposed objection. What the reviewing court determines in these cases essentially is whether the administrative position was arrived at arbitrarily. If there is any basis for it—and even where there may be conflicting opinion evidence—Federal judges are not going to lean toward permitting questionable ingredients to be marketed. They never have, and they never will.

In writing to this committee last year the FDA counsel, Mr. Goodrich, put the point very effectively in saying:

"The reluctance of courts to interfere, however, on matters of health arises both from their confessed inability to pass scientific judgments and from the disastrous consequences of a wrong decision. They, like the Department, prefer to err, if they must, on the side of safety, rather than be mistaken in holding that a poisonous chemical will be safe.

Indeed, the relative burden on the district court, as opposed to a court of appeals, is far less. As Judge Biggs suggested last year, the three judges on the court of appeals presumably each will go over a massive record to determine whether on the entire record the agency's findings can be sustained. By contrast, in the district courts, as everyone knows, the pretrial machinery results in the isolation of specific questions. These can be isolated and effectively adjudged. As to competence, I hardly suppose that one can seriously suggest that the lower Federal courts are incompetent when in their daily work they have to decide equally difficult issues.

As a matter of fact, in the present enforcement of the Food, Drug and Cosmetic Act the Federal district courts are constantly being called upon to decide issues which turn on questions of scientific fact very similar to those which would be presented under this bill. They must decide what constitute "adequate directions for use" of a drug; whether therapeutic claims for certain drug products are medically justified; whether a particular drug requires a warning statement, and what form it should take; and a host of similar scientific questions. If they are competent to deal with these questions—and the FDA has never suggested that they are not and it has had singular success in the district courts—it is difficult to see why they would not be equally competent to deal with questions presented to them under this bill.

A residual objection is that court of appeals review on administrative findings is provided in other statutes and for food standards and pesticide regulations in the Food, Drug and Cosmetic Act. Last year it was suggested that if the Administrative Procedure Act needs amendment, that statute ought to be broadly amended to permit reversal of any administrative action erroneous on the entire record rather than to determine the appropriate review tribunal for the food additive bill.

With all due deference, I suggest that the wide varieties of administrative controls under other laws do not require that precisely the same types of review be afforded in every situation. Even more, this committee is now dealing with the particular bills before it, and the problem of what is the proper review court with respect to this area, in the light of the unique problem with which the committee is here dealing, ought to be faced up to, without awaiting the resolution of far more complicated questions in the entire field of administrative law.

6. As to the desirability of providing, as does H. R. 6747, for the referral of controversial questions to an extracurricular advisory committee, we are against it because this procedure is not good government, it is confusing as to real responsibility for decision, and burdens the whole job with added delay and costs.

The National Academy of Sciences is a private nonprofit corporation operating under a Federal charter. But it is in no sense a governmental agency.

The National Research Council consists of about 300 scientists located all over the United States who are appointed by the Academy and serve on its various committees. These men are volunteers; they are ordinarily not paid; and their participation in the Council's work is necessarily only part time.

The National Academy and the Research Council work on research contracts for the Federal Government, also for private industry, and get part of their funds from private endowments.

H. R. 6747 provides, by cross-reference to the Pesticide Act of 1954, for a referral of either the whole petition or any question of fact, whenever the applicant or the Secretary so desires. Page 10, lines 4–14: In the cross-references, it is specified that the advisory committee be selected by the National Academy of Sciences. They are to get per diem and travel expenses, but not to be subject to any provisions of law covering Government officials. Ordinarily, the National Academy accepts the recommendations of the Government agency with which it deals as to who should serve on committees. If no one wants to serve, H. R. 6747 provides that the FDA may itself appoint the advisory committee.

The bill also specifies that the petitioner, for example, the Jones Co., "shall have the right to consult with such advisory committee in connection with the matter referred to it." Obviously, the FDA may also consult with it. But when, where, or how this private group is to function is not specified. Its members will be located all over the United States. They will be working part time without any regulation and with no standards. Even more troublesome, H. R. 6747 (p. 11, lines 23–25) requires that the petitioner must put up the money to pay their per diems and traveling expenses.

A further difficulty exists in that no one in the FDA may, under section 6 of H. R. 6747, reveal or use trade secrets, but this restriction would probably not apply to the advisory committee.

What is here contemplated, if not invited, is that everybody lobby with the members of the advisory committee on the question of safety. In addition, as I have suggested, even the question of "functional value" can be thrown into the advisory committee arena.

After 60 or 90 days, the advisory committee files a report. But what does that report mean? The FDA need not accept it. The people who wrote the report are not required to come and state the basis for their individual views. One of them may come and presumably attempt to tell what the others said or thought.

H. R. 6747 has conflicting provisions as to the effect of the report. But what is clear is that if the FDA wants to adopt it, the report will constitute substantial evidence supporting its administrative findings and conclusions. Page 14, lines 1-5: A further "Iron Curtain" is to be drawn.

Why is it necessary to add this flying buttress to the procedure of FDA review of pretesting data? The FDA cannot abdicate its own responsibility in safeguarding the public health. The food manufacturer, in dealing with his Government, ought not to be required, expensively and almost everywhere, to deal on this loose basis with these advisers who, however learned or willing they may be, are not Government officials.

The entire suggestion is reminiscent of the NRA Code authorities and all of the difficulties and confusion that they caused.

If these scientists are interested, knowledgeable, and available, they can be consulted and asked to testify—directly and in regular fashion—on any issue of scientific fact or opinion.

The fact that a similar system was incorporated in the Pesticide Act is no reason for including it here. The inclusion of representatives of agricultural colleges in the pesticide bill suggests that there may have been other considerations for advisory committees in that area. So far as I know, the procedure has been employed only once.

Finally, there are a number of perfecting amendments to be offered to H. R. 6747 if that bill is to be used in any way as the basis for committee consideration. Except as to one point, these will be submitted to the professional staff since they involve mostly clarifying language suggestions.

There remains, however, the problem of what to do with additives now being used and which are not generally recognized as safe and have not been approved so as to fall under the grandfather clause.

H. R. 6747 attempts to deal with these by three methods. The first is to postpone the effective date 180 days and permit the immediate filing of pretesting data if it exists (p. 15, lines 15–25).

The second is to postpone the effect of the law for 1 year on any ingredient now employed for a particular use or to an earlier date if the FDA within the year decides it is unsafe. The language (p. 16, lines 5–17) is somewhat confusing since it talks about a "final denial," but also precludes any hearing or judicial review.

Lastly, H. R. 6747 permits a 2-year extension on any ingredient now being used in the discretion of the FDA.

Since this issue is somewhat dependent on when the amendment is finally enacted, H. R. 8390 does not deal with it.

There are some who who suggest a blanket exclusion of all existing uses on the ground that the FDA has its full arsenal of seizure, injunction, and prosecution to deal with them, and a clear cut-off date is preferable without any grandfather clause. Others urge that on existing uses a 2-year period be given within which to file the pretesting data and that once this is done the exemption continue until the procedure has been exhausted.

The committee must balance the time necessary for adequate pretesting against the probable date of enactment, and the hazard of any existing use causing public injury. What is here involved is possible long-term injury from prolonged ingestion. I am confident that if any acute danger appears, FDA will, as it can, act under existing law and make immediate seizures.

On that basis, I would recommend a 2-year grace period for existing uses and a full opportunity for final determination under whatever procedure is enacted.

As a final word, I hope that nothing that I have said is taken as critical of the FDA. Its officers constitute the finest body of devoted public servants in any Federal agency. They do wonders on an inadequate budget. The canning industry occasionally, as here, may differ as to means. But over more than 40 years it has served a community of interest with the FDA in the development of sound legislation and regulations and in their effective enforcement.

Mr. AUSTERN. At the outset, sir, I would like to state the overall position of the canning industry.

The canning industry supports the basic principle of pretesting every new food ingredient so as to insure its wholesomeness and safety for the intended use.

The canning industry unqualifiedly supports H. R. 8390, the Harris bill, and H. R. 8629, the Wolverton bill. The canning industry opposes, not the underlying purpose, but the basic licensing scheme of H. R. 6747, the FDA proposal.

I shall attempt to crystallize the bases for that position, and perhaps it would be useful to the committee for me to attempt to do so in three ways:

In the first place, with your permission, I am going to try to demonstrate in nonlegal terms the practical operating differences between those two proposals.

Mr. DIES. May I interrupt just a moment, Mr. Chairman?

I want to say to the witness that I think that approach is much more helpful to the committee than reading a prepared statement, and if we can get clearly before us the mechanics of these bills, just what would be required of the food manufacturer, or the procedure, in chronological steps, that that will be far more valuable in reaching a decision about this, and I just wanted to compliment the gentleman for approaching it in that manner.

I hope the other witnesses will do likewise.

Mr. AUSTERN. I will try to do it, Mr. Dies; in short, to attempt to show you how that will work. That is the first thing I shall try to do.

Secondly, with that background of practical operation before you, I will try to discuss very briefly the 6 key issues that this committee must resolve about these 2 bills.

Quite frankly, I hope to persuade you that they are properly resolved in H. R. 8390.

Finally, if I have time, I will endeavor to suggest certain technical legal modifications to the language of both bills.

But at the outset, Mr. Chairman, I want to call the committee's attention to a paradox, and that is that everyone who comes before you is in agreement as to the need for this legislation. No one disagrees with the proposition that any new food additive whose possible

toxicity is unknown should not be employed without adequate pretesting as to its safety. No one disagrees that the information concerning the pretesting and safety should be presented to the Food and Drug Administration for its consideration in advance of using that new ingredient in any food.

I might add that, by and large, that is what the canning industry does.

Turning now to this first job, and I hope completely avoiding legal technicalities, let us see in practical operating terms how each of these bills would work.

Let us suppose that the Jones Food Co. discovers that by adding a minute quantity of a new ingredient to its product, it can make the product better. The new ingredient might improve its appearance or its looks, or it might make the product taste better or act more smoothly when used in cooking, or it might facilitate its production so that it could be made more cheaply.

Now, that new ingredient might be a chemical, but it also might be derived from a vegetable, or even from a seaweed. The point is that it is a new food ingredient.

Although some of these bills, Mr. Chairman, are entitled "chemical additive" proposals, every one of them covers every new food ingredient—animal, vegetable, chemical, biological, natural, or even something that might be developed by irradiating some common food.

Of course, recognizing that the words "chemical" and "chemical additives" are politically attractive, the committee must, I submit, at the very beginning be realistic and acknowledge and understand, in looking at the practical operations, that it is dealing with all new food additives.

Mr. WILLIAMS. Mr. Austern, may I ask you a question at this point?

Mr. AUSTERN. Yes, sir.

Mr. WILLIAMS. I asked this of another witness the other day, and did not get too clear an answer.

At what point does a component cease to be an ingredient and become an additive? How do you determine whether a component part of a food is an ingredient of that food or whether it is an additive?

Mr. AUSTERN. I would like to answer that two ways:

One, I do not see any difference; and second, I think it would have to be a very radical change. We run into that problem, sir, in the food and drug field in terms of, say, shipping a chemical to a drug manufacturer for use in simple mixing or as a chemical reagent in drug manufacture.

Mr. WILLIAMS. You see, if we approve any legislation here on this subject, we have got to define an additive, and in order to define it, I would think you would have to write such a definition which would distinguish it from an ingredient or a component part of the food.

Mr. AUSTERN. Without getting into terminology, anything that goes into a food or is intended deliberately to be added to the food—about which we do not know whether it is safe or unsafe—is covered by this bill, and should be.

I was suggesting that when you look at what a food company has to do, let us be realistic. If it has got something that it is going to

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add to its product, then it must begin to consider its situation under this legislation.

The first job of the Jones Co., sir, is to determine whether the new ingredient which it wishes to use is generally recognized by qualified people as safe for the intended use.

How does it go about that? Well, its own research people or some outside consultants will search the scientific literature, and let us assume they find nothing, one way or the other, about its safety. It is new. There is nothing in the literature about it.

And if there is any doubt, the Jones Co. can go around to the Food and Drug Administration and say, "What do you fellows know about it? Do you consider that it is an untested new food additive?"

Let us assume that there is no basis for saying one way or another that the new ingredient is safe or that, in the words of the statute, "it is not generally recognized as safe." So these new laws, whichever one you enact, begin to operate. The Jones Co. would be obligated to pretest this new ingredient before using it.

That is done by testing it on animals. Obviously you cannot use a human being as a guinea pig. So the ingredient is first tested for acute toxicity; that is, to decide whether, at the level it is going to be used, it would have an immediate adverse pathological effect.

That is only the beginning point. The new ingredient must also be tested for chronic toxicity, to determine its possible effects when taken over a long period of time.

The research work that is done on animals by the Jones Co. or its consultants must then be extrapolated to man. There are scientific techniques for doing that. In each of them, safety factors ranging as high as 100-to-1 are employed.

Now, Mr. Chairman, and gentlemen of the committee, it is usually at that point that scientific toxicological and medical judgment and, very often, plain commonsense, must be called into play.

What is the Jones Co. trying to measure in determining that an ingredient is safe for the intended use? What must the company in its pretesting be ready to establish, let us say, under H. R. 6747, to show that the new ingredient is without hazard to man?

This committee hears talk about substances which are poisonous or deleterious, and you will hear talk about something called a per se rule. That has been interpreted, this language in the law has been interpreted, to mean that any substance is poisonous or deleterious if it has a tendency to destroy the vitality of the human body.

But these scientists whom it consults will tell the Jones Co., and they will tell the committee that the concept of safety is always relative, and it depends upon the character of the new ingredient and how much of it one takes and what happens to it in the body.

As Mr. Coleman, I believe it was, suggested to the committee last week, common salt in large enough quantities is poisonous.

Wood smoke, believe it or not, contains many organic acids. There are many foods which, if eaten exclusively, would soon kill a man. There are many diets of conventional foods which, if taken over a long time, might cause serious disease.

Indeed, I think Mr. Coleman suggested that you could commit suicide by drinking ordinary drinking water.

Back in 1950, Dr. Koppanyi told the Delaney committee that from that point of view, and getting completely away from new food additives, there might be a large number of staple foods which are now eaten every day and now considered completely innocuous, that might not pass muster in extensive testing of their longtime effects.

But, anyway, going back to the Jones Co., suppose if, after the pretesting, the experts cannot satisfy themselves that the proposed new ingredient is absolutely safe even if you ate a ton of it, they can come up with a realistic and workable appraisal of the safety at a given level of use.

Of course, gentlemen, in that evaluation, those pretesting experts and the FDA must be conservative. They must play it safe, and not take any chances with the public health. And that is why those toxicity testing methods have, and should have, wide margins of safety built into them.

Last week, in New York, Mr. Goodrich, counsel for the FDA, said this on that point:

> Our methods do give us an assurance of safety which removes all reasonable doubts.

Now, that is true, even though in Mr. Goodrich's words there remains a gap between reasonable doubt and absolute certainty which science cannot cross.

But, gentlemen, that is the same kind of a doubt that now exists in the present arguments about the effect on heart disease of eating butter or about a diet which is composed exclusively of vegetables or of meat, or about the drinking of certain types of mineral water. And, if you will forgive me, I would rather not discuss the subject of whisky, because, considering its immediate and longtime effects, there might be some doubt whether it would pass.

Mr. LOSER. I wanted to get into that.

Mr. AUSTERN. I am not an expert on that, sir.

Let us go back to this practical illustration. Suppose the Jones Co., after spending a lot of money on testing and a long time, is told by reliable toxicologists that its new ingredient is safe. Suppose it is told enough to satisfy either what H. R. 6747 prescribes as without hazard to the health of man, or what H. R. 8390 says in simpler and clearer language, safe for use under the conditions of its intended use.

Let us go on to see what happens to the Jones Co. under each of these bills, FDA's and H. R. 8390.

Under the FDA bill, the Jones Co. files a petition with the FDA which sets forth all of the information it has collected on safety. In addition, and very important to remember, the Jones Co. must also set forth why it thinks using this supposedly safe ingredient will improve the product or lead the consumer to prefer it or help in its manufacture; and that is called, in the FDA bill, data bearing on the functional value of the ingredient.

What happens? On that functional-value point, the Jones Co. is somewhat stymied at the beginning. You cannot market a food containing a new ingredient until you pretest it, until it has been checked by the FDA. So you cannot determine consumer preference if you cannot market it.

And, of course, you cannot verify production economies until you manufacture it in commercial quantities.

So, in that part of its application, the Jones Co. is more or less limited to saying, "We think it has functional value," and the FDA is completely free to make its own determination.

Once the application is filed, the Jones Co., under the FDA bill, first waits 90 days. If, within that 90 days, the FDA wants more time, then the initial waiting period is extended to 180 days. Within that time the FDA reviews the safety data, and they decide two things:

First, is the ingredient in its intended use safe? And the second is whether, in the FDA's opinion, it really has functional value; that is, the FDA somehow decides whether it will be useful to the consumer in improving the product or in making it more appealing or convenient for the consumer's use or improving its processing, storage, or handling.

Of course, how the FDA determines that functional value for the Jones Co. or the consumer is wide open, because there is no definition or standard of how they do it in H. R. 6747.

Well, at the end of the 180 days, the FDA then issues an order, and the order either licenses the intended use of the ingredient or the FDA denies the application and refuses to license the use of the ingredient.

When the Jones Co. gets an order denying its application, it can, within the next 30 days, ask that the question be referred to what is called an advisory committee, and that is composed of experts from the National Academy of Sciences; and if they cannot be found to serve, the advisory committee is selected by the FDA.

Of course, the Jones Co. can go around and lobby with the advisory committee about safety. This FDA bill, Mr. Chairman, gives the company the right to consult with the advisory committee, but it does not tell how they do it or when or where, or what happens if the advisory committee will not talk to the experts from the Jones Co.

In any event, after another 3 months, the advisory committee files its report and its recommendations.

I had better mention, also, that before the Jones Co. can go to the advisory committee it has got to put up the fees to pay their expenses.

Well, gentlemen, when the FDA gets the report from the advisory committee, H. R. 6747 provides for another month to consider it, and then the FDA either modifies the original order or issues the order as it first issued it.

Well, suppose the Jones Co. is still turned down. What is the next thing it can do? Within a further 30-day period it can file its objections and ask for a public hearing in the FDA. In other words, please remember that, under this bill, you get your hearing after you have been turned down, not before, and you get it in the FDA which has turned you down.

Well, suppose the Jones Co. thinks it is right, and it asks for a hearing. It then waits a further long time for the public hearing to be scheduled in the FDA.

H. R. 6747, gentlemen, does not specify the time, and it can go fairly long before the FDA gets around to scheduling the hearing; and, of course, at the hearing in the FDA, the Jones Co. presents its experts; presumably the Food and Drug presents its experts.

Of course, at that administrative hearing in the FDA, there is no judge. Instead, there is a lawyer from the FDA who presides. And I do not think, Mr. Chairman, I will change the definition I suggested last year that that hearing officer is merely a recording instrument who keeps order. He decides nothing.

But what happens? The Jones Co. application and the record at the public hearing is then considered again by the FDA, once again by everybody in the FDA, including the FDA witnesses who appeared at the hearing and gave the opposing testimony.

After a further long time, since again the FDA specifies no period for action, the FDA people get up a series of administrative findings and conclusions.

By the way, even if they then decide that the Jones Co. can use the ingredients, you have got to wait another 90 days before their order becomes effective. But let us assume, to carry this out, that the Jones Co. is still turned down. Let us assume further, if you will, that they think that the FDA refusal is unwarranted, and they think that the careful pretesting they did warrants the licensing of the new food ingredient, both because it is safe and because, despite what the FDA thinks, the Jones Co. thinks it serves a useful purpose.

Well, that brings us to court review.

Of course, Mr. Chairman, if the Jones Co. wants to go to court on a question whether a new ingredient is poisonous or safe, it risks serious adverse publicity. If the Jones Co. has a competent lawyer, it will probably be told a couple of other things.

The first one is that the FDA's determination as to whether this new ingredient has functional value, tasty, appealing, useful, is just as controlling under H. R. 6747 as its determination on safety.

Now, of course, any question as to whether an ingredient is functionally useful is hardly a medical judgment. But they had better be told that, in any court presentation, the issues as to safety and functional value will be pretty well mixed up.

The Jones Co. also will be told that if that report from the advisory committee was against it, even though there are no records as to what anyone said to the advisory committee privately or publicly or in any other way, that report alone will be a pretty tough stumbling block in any court review.

But most important, Mr. Chairman, under this FDA bill, the Jones Co. will have to appreciate that the reviewing court will never see any witnesses, but will only have a paper record, and that the working rule will be that if, on the whole record, there is any evidence to support the findings of the FDA, they will stand.

Mr. DINGELL. Are not those words "any substantial evidence"?

Mr. AUSTERN. Any substantial evidence.

Mr. DINGELL. The word is any "substantial" evidence.

Mr. AUSTERN. The words in the proposal are "any substantial evidence."

Mr. DINGELL. There is a difference between "any substantial" and "any" evidence; am I correct?

Mr. AUSTERN. I should say that, in the Universal Camera case, Mr. Dingell, that phrase has been subjected to interpretation, and it is——

Mr. DINGELL. It means more than hearsay. It means actually some convincing——

Mr. AUSTERN. More than a scintilla.

Mr. DINGELL. It means some convincing and it means some legally probative evidence, not hearsay, not speculation or guess, but actually valid legal evidence; am I correct?

Mr. AUSTERN. Yes.

I would like, if I may, sir, to come to that point when I deal with the specific issue of court review. I am endeavoring here to give you a bird's-eye view of operation. I do not mean to be evasive. I will come back to it.

Mr. DINGELL. I appreciate that.

Mr. AUSTERN. I would like to finish what would happen to the Jones Co., what would happen to them under the FDA bill, by saying one more thing:

Realistically, the Jones Co. had better appreciate that no matter what the form of court review may be, it will have the proverbial chance of a snowball in getting any judge or group of judges to overrule the FDA when it is backed by this whole paraphernalia of an administrative record, findings and conclusions.

Now let me take the other half, and look very quickly at what the Jones Co. would do under H. R. 8390.

It would have to make the same initial determinations or inquire of the FDA as to whether its new ingredient was generally recognized as safe for the intended purpose. It would have to make the same prolonged and costly scientific pretesting as to acute and chronic toxicity. It would have to file all of the same safety information with the FDA, except that this unavailable knowledge, proving that the ingredient might be liked by the consumer or useful in production, would not be called for.

Under H. R. 8390, the only question is whether the ingredient is safe for the intended use. And under the bill H. R. 8390, the Jones Co. cannot use the new ingredient unless and until it has submitted its data to the FDA and it has gone through the process.

The FDA, under that bill, gets 120 days to examine the information, unless in the course of the Jones Co. talks with the FDA it is agreed that more time is needed.

Realistically, in almost all cases where more time is needed, the Jones Co., of course, will agree that the FDA can have more time. Otherwise, you get turned down immediately.

Well, under H. R. 8390, the FDA examines safety. It does so as broadly and comprehensively as it can, and when it is ready it sends to the Jones Co., by registered mail, a notification that the new ingredient has been pretested enough and is considered to be safe, or that the FDA is not satisfied that it is safe, and an indication of why it is not satisfied.

In addition to that, under H. R. 8390, the FDA might publish a notice that it has made that conclusion, that that ingredient in this use is not safe, and thereby put everybody else on notice of its position.

Well, let's go on with the Jones Co. under H. R. 8390.

If it is turned down, the Jones Co. cannot begin to use the new ingredient, even though it thinks it is right. If it wants to do so, it has to give the FDA at least 3 months' additional notice; and it has to tell it, with respect to any food in which it is going to use the ingredient, how much and where and to whom the challenging shipment is going.

And if the FDA wants to keep the new food ingredient off the market, the FDA goes to the district court and gets a restraining order, stopping shipment while the case is being tried. Of course, Mr. Chairman, that restraining order stops the Jones Co. from using the new food ingredient, but the Jones Co. can then get real judicial review within a reasonable time.

Let me conclude on this illustration with the same note:

Under H. R. 8390, the Harris bill, the Jones Co. would still have to understand that the chances of getting the Federal courts to second-guess the FDA on the question as to whether a proposed ingredient is safe would be as remote as the most distant star.

Indeed, reversing the FDA under H. R. 8390 would be far more difficult, because the only issue involved would be that of safety and the public health. The Jones Co. had better know that only if it can demonstrate completely and persuasively that there were no doubts about safety and that there has been a plain abuse of administrative discretion could it possibly prevail.

But even though under H. R. 8390 the Jones Co. can get a real judicial trial and can cross-examine the FDA experts before a real, live judge, again its chances of overturning the FDA on the FDA's assertion that this new ingredient is a hazard to man, I think, would be about one in a hundred thousand.

And, lastly, they had better be told under H. R. 8390 that even if the FDA could not make the restraining order stick in the first instance, it would always be free on some additional information to seize the goods, to bring another injunction action, and even to prosecute the Jones Co. criminally.

Therefore, to finish the illustration, practically whatever comfort the Jones Co. might take from the absence of the hocus-pocus about advisory committees or from the opportunity to get real judicial review within something less than 2 years, the practical result, I suggest, getting away from legal technicalities, is that unless it can administratively satisfy the FDA that this new ingredient is safe it will remain civilly and criminally prohibited from using it without FDA clearance.

What else would happen?

For the public, the result under H. R. 8390 is exactly the same. No new food additive can be used until it is pretested, until it is determined that it is safe, and probably more important for the public will be the fact that the question of what is useful or desirable or tasty or appealing in the diet is left to the consumer to decide and not blocked by this licensing system buried in these administrative findings in this machinery.

For those interested in maintaining some basic concepts of free enterprise, the difference between responsibility with effective and immediate control and the deadening effect of licensing would be regarded as well worth preserving.

Mr. Chairman, so much for the way the two proposals would work for a food company.

May I turn now quickly to the specific issues which are before this committee and which you must resolve in this bill. There are six of them:

1. The controlling definition that should be included.
2. The so-called grandfather clause.

3. The argument about functional value: Should you have it or not?
4. The issue of licensing versus direct enforcement by the FDA.
5. What should be the reviewing court.
6. Whether this advisory committee complication is necessary and useful.

First, as to the definition:

We think that there is no escape, Mr. Dies—and you were worried about this last year—from using that admittedly vague standard of "generally recognized by qualified experts." But we suggest that there is very little to worry about on that point, because, as the new drug section suggests, unless a fellow is absolutely certain that his ingredient is safe, the risk of criminal penalties will result in his asking the FDA whether it thinks the new ingredient falls within the act or is generally recognized by qualified experts as safe.

Apart from calling a spade a spade, and a food additive bill a food additive bill and not something about chemicals, there really appear to be two differences in the definition between the FDA proposal and H. R. 8390.

H. R. 8390 states that a food is covered because it becomes or could reasonably be expected to become either a component of the food or to affect its characteristics.

Now to return to your question, Mr. Chairman, in my book, anything that is put into the food becomes a component of it, and I do not care whether you define it as an ingredient or a component.

H. R. 6747, in the definition section, has a great deal more language. I do not know what the difference in the language is, unless it turns on the question of adding a new ingredient deliberately, or getting it accidentally into the food, and I think everyone will agree, including the FDA, that what you are dealing with in these bills is a deliberate, an intentional addition of something, or something which ordinarily will get into the food, and not with accidents.

Now, the second small difference between the definitions in the two bills is that the FDA proposal attempts to spell out with a lot of words what is a qualified expert; whereas H. R. 8390 simply specifies that they must be qualified by experience in evaluating the safety of food.

The second form seems better to me, because the additional language about toxicity and other potentiality for harm, it seems to me, confuses the basic idea of "safe for use."

Now, as to the grandfather clause: The principal change in H. R. 8390 is the inclusion on page 2, lines 15 and 16, of the words "formal or informal" and "shown to have been."

Let me explain the reason for that, and it is very simple to state: Over the past 19 years, gentlemen, many manufacturers have gone to the FDA and inquired about the propriety of using a particular ingredient. They have very often been told informally that the use was proper, and they just have not bothered to get a confirming letter.

We believe that if anybody can demonstrate that he got informal approval from the FDA or the Meat Inspection Division, he ought not to be required to go through all of these procedures. And under H. R. 8390, the burden remains on him to demonstrate that he got that informal approval, subject to criminal penalties if he cannot do it.

As to functional value, there is very little for me to add. The industry I represent, gentlemen, is adamantly opposed to having any

Federal agency determine what the American consumer likes or dislikes, or what serves a useful purpose in any food.

It is no answer to talk about the food standards sections. They involve different considerations. They have certain flexible experimental permit procedures. And, indeed, at this moment there is a great big argument about that whole subject of food standards.

But I would like, with your permission, to point out a few more things about this functional value point as it appears in H. R. 6747, the FDA bill.

In the selection of the advisory committee, in the FDA proposal, it is provided that that floating advisory committee can have referred to it any question of fact.

Well, it is bad enough to have a Federal bureau determine what is attractive or appealing for a consumer in a food. It is compounded heresy, I submit, to enact a law that permits that question to be loosely referred to a committee of scientists.

This determination of functional value is not scientific. It is probably esthetic and inevitably economic. And it ought to be answered on the grocery shelf or by the consumer in the kitchen, and not by either a Federal bureau or a learned society.

Lastly, this final language on page 8, line 15, of the FDA proposal, seems to me proves too much. You will remember those words say, in effect, that if a new ingredient is safe, functional value shall not be considered.

Well, the whole point of this bill is to determine what is safe and what is not safe, within reasonable and workable limits. And we appreciate that the FDA must and will be conservative in determining safety.

But once, gentlemen, it is determined that for a particular use an ingredient is without hazard to the health of man, that should be the end of the matter without this functional value inquiry.

This committee has expressed considerable interest in this basic question as to whether there should be a licensing system or whether the pretesting, filing of the information, and immediate automatic injunction provisions of H. R. 8390 should be employed.

Now, may I emphasize, sir, as I am afraid has not been appropriately emphasized, that H. R. 8390 does not take away any enforcement weapon which now exists for the FDA. It does not weaken or impair the FDA's present power to seize, to enjoin, or to prosecute criminally. What it does do is to create brandnew criminal and civil prohibition against using any unknown ingredient without pretesting to determine safety, and without giving the FDA 3 months or more, by agreement, to verify that pretesting work. If the FDA is not satisfied, the ingredient still cannot be used for 3 more months, and if a court test is wanted, the FDA is given the basis for an immediate restraining order that prevents its use until the court review is finished. The public is protected without a complicated licensing system and without administrative mumbo jumbo.

The trouble is, Mr. Chairman, that people loosely talk about analogies. They talk about the new drug section. Well, the new drug section is wholly different, and as many members of this committee have come to appreciate the way the new drug section is administered, it is rather like a patent law.

Let me illustrate that. If one manufacturer establishes in his new drug application that the drug is safe, and he presents abundant clinical data to prove it, and he gets approval, another manufacturer cannot get the identical product approved unless he repeats the same clinical work.

The new drug section analogy seems to us to be wholly inapposite here, and if you are going to use an analogy, by George, you ought to use all of it. The new drug section puts the review in the district court.

There is no point—because I want to offer a suggested amendment here—there is no point, I trust, sir, in my making a long speech about the basic orientation of American law toward freedom of enterprise, and against prior Government licensing.

If the committee is interested, I have given to the professional staff a long paper presented in 1952 to the Institute of Food Technologists.

But what seems to us to be simple and vital, and that must be understood, is that the canning industry and, insofar as I know, many important groups in the food industry, are unwilling to accept a system whereby what it may pack and how it may pack it and how it may operate are going to be subjected to Federal licensing controls.

Only where the paramount public interest cannot otherwise be protected, will those objections be waived, and in this instance we submit that H. R. 8390 affords abundant public protection.

Let me show you why, quickly.

If you want to interrupt me, sir, I see Judge Biggs has arrived.

Mr. WILLIAMS. How much more did you have?

Mr. AUSTERN. I hope to get done in 15 minutes.

Judge BIGGS. Mr. Chairman, I have all day. I suggest the witness will continue. I am at your disposal.

Mr. WILLIAMS. It is very doubtful we will be able to meet this afternoon because we have some rather important legislation up on the floor.

Mr. LOSER. I wonder how long the judge's testimony will require.

Judge BIGGS. I should think I could cover it adequately in 10 minutes.

Mr. WILLIAMS. Proceed, Mr. Austern.

Mr. AUSTERN. All right.

I had suggested, sir, that only where the paramount public interest in protecting the public health cannot be protected will we ever give up on this concept of Federal licensing of the food industry.

I had suggested to the committee that H. R. 8390 fully protected the public.

In the one case in thousands in which a manufacturer who believes, honestly believes, that his pretesting has established safety, and that the FDA has acted arbitrarily, and who is willing to risk the publicity and invite a judicial test, he must give the FDA, under penalty of criminal prosecution, at least 3 months' notice, and furnish a complete basis for an immediate restraining order, and that will effectively stop the use of any ingredient which the FDA does not think is safe.

Now, gentlemen, in some discussions the question has been raised about the status of another manufacturer acting independently of this applicant that I have called the Jones Co. and to the possibility that this other manufacturing company might not be prohibited from using the ingredient or even know about one which has been approved.

That suggestion, Mr. Chairman, has led to a further suggested provision that you might want to include in 8390, and perhaps it ought to be included not only to meet the theoretical objections advanced but to avoid some of the difficulties under the new drug section, and that would be to insert on page 6, line 13, in the section that deals with the Secretary notifying the Jones Co. this provision:

Whenever the Secretary notifies any person who has submitted pretesting data on any new food additive that, in his opinion, such additive has been adequately pretested and is safe for the conditions of its intended use, he shall forthwith publish in the Federal Register an announcement of the ingredient and the conditions of its use which have been so approved.

Perhaps you might want to make a comparable addition to (e), so as to provide that if he revokes it he also publishes the revocation.

The effect of that addition will be this: If any ingredient is approved as safe for one company, it will then be open for use by all other companies. The pretesting and clinical work that costs so much money and takes so much time will not have to be unnecessarily duplicated.

If the use of an ingredient, gentlemen, is subject to protection under the patent laws, the company that develops it can get a patent. It is not the function of any food and drug law to establish supplementary protection to the patent system, and once that addition is provided I submit that all theoretical difficulties with subsection (g), the injunction provision of H. R. 8390, will disappear.

Let us get it straight: If the ingredient has been approved by the FDA as safe, the applicant, and everybody else, will be permitted to use it. If it has not been approved, no one else will be permitted to use the new ingredient unless he does the pretesting and files his information and goes through the entire procedure.

That is the basic prohibition of this bill, and, of course, that disposes of any objection that a restraining order and an injunction against one man does not bind everybody else; for everybody else is criminally prohibited by the law itself and in that respect H. R. 8390 and H. R. 6747 are identical. The criminal penalties apply to the same prohibited conduct, namely, using a new ingredient that has not been pretested and the pretesting data.

There is one other objection that you may hear, indeed, I rather anticipate that you will. Some people may be concerned that this injunction provision in H. R. 8390 leaves it to the discretion of a Federal court whether a restraining order should be issued.

Well, sir, that objection is wholly unrealistic to anyone experienced in this field. In the one case in thousands in which this injunction provision would come into play, because a manufacturer deliberately seeks a court test, there can be little doubt that the United States district could will issue a restraining order on the FDA representation that the ingredient is not safe.

Those requirements are built into the section. But again, if anybody wants to chase ghosts and the committee wants to button that point up, namely, that some judge will not issue a restraining order while the case is being tried, you can very simply cure it by including at the end of the first sentence in the injunction section on page 7, line 11, the following short sentence:

If any injunction proceeding is instituted with respect to such additive or any food bearing or containing it, it shall be a violation of section 301 to ship that additive or such food unless and until the injunction suit is finally determined in favor of the defendant.

You can get the same result by amending section 301. But in either event, the institution of the injunction sought by the FDA would automatically and completely foreclose shipment by the defendant of any ingredient that the FDA did not want, and, of course, everybody else, as I have suggested, is basically prohibited from using it.

If you want to have technical symmetry, if you add that sentence I have suggested you can put the word "also" in the restraining order section, so that in addition to being a crime to use the ingredient while the court case is going on, it will also be contempt of court.

As to what should be the reviewing court, I would like about 3 minutes on that. In the first place, there is a threshold question. I suspect that every man on the committee is ready to ask me this question: If successfully overturning the FDA in court is so remote and hopeless a task, why should anybody care whether they get judicial review before a judge who sees the witnesses or merely a review on paper findings in the CCA?

Well, the answers are real and important. In the first place, I suggest that it is largely because anyone who takes on the FDA on the issue of safety has almost an impossible assignment. It is principally because, as I suggested last year, that the FDA has such momentum in court that a real trial, with live witnesses heard by a real judge seems to me to be essential.

As Judge Biggs told this committee last year, Court of Appeals review is on the findings of the agency and the entire supporting record. As he said, questions of fact are not reviewed except on the whole record.

But, gentlemen, those agency findings that are prepared by the FDA staff, and it is only natural that they are formulated, stated and prepared strongly to support the FDA position, and of course there is no opportunity to cross-examine anybody in the CCA.

If you look at the FDA proposal, H. R. 6747, you will see it in cold words, the findings of the FDA are prepared after the agency holds its own hearings, before its own presiding officer, and the judicial review they want is a paper operation, done on a vast record.

The second reason why this question of what court you get is important, is that what happens in court in a particular case is not as important as the salutary effect of real court review on all agency action.

I have often urged that the only reason for having any cross-examination is to expose administrative action to public cross-examination. He who regulates and he who is going to refuse arbitrarily to accept good faith scientific evidence ought to be made to appear publicly and say why, and if those who make the administrative decisions know that where they act arbitrarily they might be publicly interrogated before a trained judge, the indirect effect on careful agency action is fully felt.

I have spelled that out in some letters to this committee.

So far as I know, Mr. Chairman, there have only been three objections to this form of court review in the district court. The first suggestion is that the lower courts will be burdened. Well, with all due deference, and I hate to be too bumptious, that is nonsense. As I tell you in my statement, under the new drug provisions there has been one court review, unsuccessfully prosecuted in over 11,000 new drug applications extending over 19 years.

This objection that the courts are going to be burdened seems hardly warranted.

The next objection is that the Federal courts are somehow incompetent to decide these "scientific questions of fact."

There are many answers to that one. As I pointed out in a letter to the committee last year, what the reviewing court, and I do not care which one it is, essentially determines in these cases is whether the FDA got where it is arbitrarily. If there is any basis for the refusal, and even where there may be conflicting opinion evidence, Federal judges, Mr. Chairman, are not going to lean toward permitting questionable ingredients to be marketed. They never have, and they never will. And in my statement, I quote my friend Mr. Goodrich on the very same point.

One other thing: The burden in the district court as opposed to a circuit court of appeals is far less. Last year, Judge Biggs suggested that the three judges of the circuit court of appeals each will go over this massive record to determine whether on the entire record the agencies' findings can be sustained.

By contrast, in the district court, as everyone knows, the pretrial machinery results in the isolation of specific questions, and those can be segregated and effectively tried.

Now, as to competence, I do not suppose anyone is really serious about that, but the fact is that, as this committee knows, that in the enforcement of the act, the Federal district courts are constantly called upon to decide the very same questions.

You will remember the district courts must decide under this law what constitutes adequate directions for the use of a drug. They must decide whether therapeutic claims for a drug are medically warranted; whether a particular drug requires a warning statement, and what form it should take, and a whole host of similar questions.

If they are competent to deal with those questions, gentlemen, and the FDA has never suggested that the district courts were never competent and the FDA has had singular success in the district courts—they almost never lose—it is difficult to see why the district courts cannot deal with the questions here presented.

Now, there is a residual objection which I will sum up and it is spelled out in my statement, which is: Why worry about this now? Why not wait to amend the whole Administrative Procedure Act? And I think the answer to that is, that there are so many different kinds of administrative action that you cannot say that one rule will cover them all, and I submit you have got this problem before you under this unique bill now.

To conclude, sir, I want to talk about this advisory committee. I want to state the position we have on it. We are against it because we think that procedure is not good government, it is confusing as to real responsibility for decision, and it burdens the whole job with added costs and delay.

Just what is it about?

The National Academy of Sciences is a private nonprofit corporation acting under a Government charter, but it is in no sense a Government agency. The National Research Council consists of about 3,000 scientists, located all over the United States, who are appointed by the Academy to serve on its committees.

Mr. O'HARA. Three hundred.

Mr. AUSTERN. That is a typographical error, sir. I do not know how that happened. It is 3,000.

Those men are volunteers. They are, ordinarily, not paid, and their participation in the council work is only, and necessarily only, part time.

These two groups, the National Academy of Science and the National Research Council, work on research contracts for the Federal Government, but also for private industry, and they get part of their funds from private endowments.

The FDA bill provides that there shall be referred to an advisory committee, either the whole petition or any question, and it provides further that if there is a reference, you pay the per diem and the travel expenses of the committee.

It is no secret that ordinarily the National Academy of Science consults the Government bureau with whom it is dealing as to who should be on the committee; but there is no doubt if no one wants to serve under this bill the FDA appoints its own committee and, of course, as I pointed out earlier, the bill provides that the Jones Co. can consult with members of the advisory committee.

Obviously, the FDA can also consult with it, but when, where, how that private group is going to function is not specified. Its members are located all over the United States, and they will be working part time without regulation or standards.

As I say, you have got to put up the money. In my statement, I point out also that I am not sure they are even bound to maintain trade secrets.

Now, gentlemen, what is there contemplated, if not invited, is that everybody lobby with the members of the advisory committee on the question of safety and, in addition, under FDA proposal, even this issue about functional value can be pitched to the advisory committee, and after 60 days, you will see, this advisory committee files a report.

What does that report mean? The FDA does not have to accept it. The people who wrote the report are not required to come and say what each of them individually determined, but only one fellow is supposed to come and report.

But whatever may be the conflicting provisions in the bill, what is clear is that if the FDA wants to adopt the report, it constitutes substantial evidence to support its findings.

Now, as far as we are concerned, with all due deference, gentlemen, we ask why is it necessary to add that flying buttress to the procedure of FDA review of pretesting data on safety?

The FDA cannot abdicate its responsibility to protect the public health, and the food manufacturer, in dealing with his Government, ought not be required extensively and everywhere to deal on that loose basis with these advisers, who, however learned or willing they may be, are not Government officials, and this bill says they are not.

Mr. O'HARA. Will the gentleman yield at that point for one question: Who determines the qualifications of these experts.

Mr. AUSTERN. Well, either the National Academy or the Secretary. I am sure the Jones Co. does not get into the act to decide who should be on the committee.

The whole thing, Mr. O'Hara, is reminiscent of the NRA Code authorities with all the confusions and difficulties they created, and I will end up by saying that if those scientists are interested, knowledgeable, and available, they can be consulted and they can be asked to testify directly in regular fashion on any issue of scientific fact and opinion.

I have a number of suggestions, largely having to do with one tough problem you have got, and that is what do you do with these ingredients that are now being used, which are neither generally recognized as safe and which do not fit under the grandfather clause?

I think—I hope—the statement is clear on that, and I see I have run over my time.

Any questions?

Mr. DIES. We thank you for your very clear and enlightening statement. I am sure it has been of great assistance to the committee.

Mr. Rhodes, do you have any questions?

Mr. RHODES. No questions.

Mr. DIES. Mr. Wolverton, do you have any questions?

Mr. WOLVERTON. I have no questions. I would like to make a suggestion. I agree with you there has been a very enlightening statement which has been made by the witness. I would think it would be helpful to the committee, certainly it would be to me, if the witness would make a summary of the points that he has made that would cover a page and a half or so of typewriting and with possible reference to your statement where those questions are dealt with more fully.

But what I am seeking is a summary of the points that he has made, so that we can give our attention to such of them as we consider important.

Mr. AUSTERN. I will do that, sir.

Mr. DIES. Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman, I was just wondering, the witness made a very comprehensive statement, but I think he failed to discuss the Delaney bill and Mrs. Sullivan's bill, and also the other bill that is before this committee authorized by Mr. Fulton of Pennsylvania.

Did you read those bills, sir?

Mr. AUSTERN. Well, I will say, Mr. Dingell, I have got them all. I would not want to trespass on your time.

As to the Delaney bill, H. R. 4015——

Mr. DIES. I want to say we have got to hear Judge Biggs, and perhaps it would be better to have him back another time when he can discuss it. I do not see how we can get into a discussion of those bills and hear Judge Biggs.

Mr. DINGELL. Very well, sir.

Mr. AUSTERN. I want to say, sir, the committee staff did make this comparison, and maybe to answer it in a sentence and get done with it, I think the Delaney bill in basic pattern follows the FDA bill. It does mention carcinogenic and a few other types of toxicity. I think they are all covered in safety.

My friend Mr. O'Hara's bill is substantially the same as last year. It has certainly attractive definitions of safety and use, and so forth. It has the old declaratory judgment concept that the committee heard last year. I do not think I could add anything to that discussion.

Mr. DIES. Mr. Schenck.
Mr. SCHENCK. No questions.
Mr. DIES. Dr. Neal?
Mr. NEAL. No questions.
Mr. DIES. Mr. Loser.
Mr. LOSER. Nothing at all, sir.
Mr. DIES. Mr. O'Hara.
Mr. O'HARA. I am glad you administered the obsequies to H. R. 366 as briefly as you did, Mr. Austern. [Laughter.]
Mr. O'HARA. I spent a lot of time on that bill. I think it is the first bill that was introduced on this subject that I can recall, several years ago. I have spent a lot of time on that, and I have no pride of authorship, but I do think it had some good sound commonsense fundamentals in it.
Mr. AUSTERN. I supported it to the best of my ability last year, Mr. O'Hara.
Mr. O'HARA. And I thought very beautifully, Mr. Austern.
Mr. AUSTERN. But it did not come to pass and the committee has to solve this problem.
H. R. 8390 is not a canning industry bill, it is not my bill. It tries to distill all the things that were said by the FDA and the industry and members of the committee. That is about all I can say on it.
Mr. DIES. Well, we thank you.
Judge Biggs, will you please come forward?

STATEMENT OF HON. JOHN BIGGS, JR., CHIEF JUDGE, THIRD JUDICIAL CIRCUIT, APPEARING IN BEHALF OF JUDICIAL CONFERENCE OF THE UNITED STATES

Judge BIGGS. Mr. Chairman and gentlemen, I want to thank you for affording me this opportunity to appear before you.
My name is John Biggs, Jr. I am chief judge of the Third Judicial Circuit of the United States, which makes me a member of the Judicial Conference of the United States which, as you gentlemen know, is comprised of the Chief Justices of the United States and the 11 chief judges, representing the respective circuits.
Under the Administrative Office Act, it is the duty of the Conference to make recommendations to the Congress, and I am here today in precisely the same capacity that I appeared last year before this committee, to express the views of the Conference respecting the bills which are presently before this body.
I might say that I am a proponent of this legislation but I am interested only in what might be termed the judicial provisions which relate to the legislation.
These bills fall into three categories. I will deal first with H. R. 366, Congressman O'Hara's bill, H. R. 8390, which I believe was introduced by Mr. Harris, Congressman Harris, and H. R. 8629, introduced by Mr. Wolverton.
These bills, all of them, as I read them, provide for the evaluation by the Secretary in order to determine whether pretesting procedures have been adequate and whether the proposed additive can be correctly and properly made use of.

H. R. 366 then provides for a de novo judicial review under the Declaratory Judgments Act, which, of course, is a well-known method of having determined legally de novo questions of law and fact.

H. R. 8390, to which Mr. Austern has devoted a good deal of his testimony, and H. R. 8629, provide no specific review, judicial review, but do provide that for the Secretary to prohibit the use of an additive in interstate commerce, he has to embark on an injunction proceeding in the appropriate United States district court and that proceeding would, of course, be a de novo proceeding.

It would seem to me, and it seems to the Conference, I had better strike myself out—it would appear to the members of the Conference that there is here, as there are in some of these other bills which I shall refer to, a major question, and that question, Mr. Chairman and gentlemen, is whether or not you are going to have the courts, the United States district courts performing administrative functions.

Using H. R. 8390 as an example, as I have said, an evaluation is made by the Secretary.

Precisely what an "evaluation" is, I am not entirely sure, but it certainly contemplates something which is very close to a day in court, because the manufacturer, or the shipper or the person who adds the additive to the food, has full opportunity to present, by way of memorandum and statements, everything which probably would be essential to prove his case.

It does not provide for a hearing in the sense that that term is ordinarily used in law. It does not provide, so far as I can see, for witnesses to be heard, and for findings of fact to be made, as would be done in a strictly legal proceeding.

But it does provide for an evaluation, and that evaluation would seem to me to cover pretty much the same ground and the same function, although I want to say perfectly frankly as to that, I could not be entirely sure.

I am not sure how a court would construe the word "evaluation," but at any rate it provides an administrative procedure whereby the use of the additive and the desirability of the additive can be tested.

But then, having had that which is somewhat the equivalent of the day in court, these bills provide for going into court and having a de novo hearing, either by way of the Declaratory Judgment Act, or by an injunction proceeding brought in a United States district court in the usual way.

Of course, this represents a very strong break from tradition, and the Conference realizes, and I realize, that this is a question of policy, one of grand policy which the Congress must itself determine.

If it is to be the fact that there are to be de novo hearings on the type of additive to be used, in the United States district courts, I must really strongly disagree with my friend, Mr. Austern, who testified on this subject a few minutes ago.

You will need a very substantial additional number of United States judges.

At the present time, as you gentlemen are probably aware, I am sure you know it, we have pending in both the House and the Senate, recommendations by the Judicial Conference of the United States for 42 additional judges, 3 circuit judges, and 39 United States district judges.

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And of recent date, it has become quite apparent that there will have to be another and a fourth circuit judge, but we are having trouble even in getting the original number of judges requested.

Quite recently we had on appeal in our court the case of the *Atlas Powder Company* v. *Ewing*, which was decided by an opinion in 210th Federal Reporter, 2d series, page 347. Atlas Powder Co. had an additive to bread, a bread additive, which made the bread seem extremely fresh and good, and the Secretary determined that it was not a safe additive, and Atlas appealed to our court.

I did not sit in the case, but under our practice all opinions are given to all judges who did not sit as well as to those that did, and I went into it very fully, particularly on a petition for rehearing, and there was not any doubt in my mind that to take that record, to try that case, not on appeal but as it would have been presented in a United States district court, would have taken many days. It was a very large record indeed.

Of course, the United States district courts can do that sore of thing if Congress decides that they should, but it is not a desirable thing, in my view, or in the view of the conference, because, as was said by Mr. Chief Justice Hughes (and I quote this from a speech made by the Honorable Alben Barkley on the floor of the Senate on May 6, 1940), then a practicing lawyer and delivering a speech at Elmira:

> You must have administration and you must have administration by administrative officers. You cannot afford to have it otherwise. Under the proper maintenance of your system of government and in view of the wide extension of regulating schemes which the future is destined to see, you cannot afford to have that administration by your courts. With the courts giving a series of decisions in these administrative matters hostile to what the public believes, and free from that direct accounting to which administrative officers are subject, you will soon find propaganda advocating a short-term judiciary, and you will turn upon our courts, the final safeguard of our liberties, that hostile and perhaps violent criticism from which they should be shielded and will be shielded if left with the jurisdictions which they were intended to exercise.

I think Mr. Chief Justice Hughes was a wise man, and so was former Vice President Barkley, who quoted that speech on the floor of the Senate.

If we are going to have courts perform administrative functions, we not only will have to very substantially increase the number of the judges, but you are putting them in a field where it would be extremely difficult for them to function, and if you do this with these bills, I can see that you will break the line right down the entire distance of the administrative agencies.

You have, first, these bills; then you will have situations where practically every administrative agency will make evaluations or some form of determinations, and then there will be reviews de novo in the United States district courts.

Let me pass very rapidly to the second lot of bills here, which are H. R. 7700, H. R. 7798, and H. R. 7938.

All of these provide that the orders of the Secretary may be appealed to a United States district court.

Now, that is an appeal, and it provides that the United States district court may send the record back for additional evidence.

Then, after there has been a decision on appeal by the United States district court, which ordinarily does not perform appeal functions, then, of course, by law there is an appeal from the United States

district court to a United States court of appeals, the appropriate court of appeals, and then, of course, by way of certiorari, to the Supreme Court of the United States.

I think, gentlemen, that it would be better, if you are going to have an appeal on the record, that that appeal be taken, as all of these appeals ordinarily are from administrative agencies, to the respective courts of appeals who, if they find the record insufficient, may send it back to the agency for further testimony.

Here, under the three bills that I named, you will have two appeals, as a matter of right; one, to a United States district court, the other from that United States district court to the court of appeals of that circuit, a duplicate appeal, which seems to me not at all desirable.

Now, H. R. 6747, and H. R. 8112 provide for determination by petition by the Secretary for the issuance of a regulation respecting an additive, with reviews by the appropriate court of appeals.

As I read the bill, my time in passing upon these has been comparatively short, you have a review provision which would seem to be adequate and in line with the ordinary review provisions from other agencies.

Now, as I said before, Mr. Chairman and gentlemen, this is a question of grand policy that the committee has before it, and which the Congress has before it.

But, as I read the provisions of the three bills that I first named you will depart from the practice and the law as it has been up to this day, and you will put in the United States district courts functions which, up to this time, have been administered by administrative agencies, and I am afraid that if that comes to pass, you will break down the entire line of review of administrative agency decisions.

There is no reason for doing that in respect to decisions by the Secretary, and not doing it in respect to other agencies, such as NLRB or the Federal Power Commission or the Securities and Exchange Commission rulings, and I think you are going to require a great number of judges to do it, and I am afraid it really is not a desirable thing to do, as Mr. Hughes and Senator Barkley pointed out.

I will be glad to try to answer any questions, let me put it this way, that I can.

Mr. WILLIAMS. Judge, I am glad to say that I have had an opportunity to hear you this morning.

Judge BIGGS. Thank you, sir.

Mr. WILLIAMS. I was not a member of the subcommittee during the last Congress, and I did not have the benefit of hearing you during that Congress.

Judge BIGGS. Thank you, sir.

Mr. WILLIAMS. I am personally glad that I had the opportunity this morning.

I am sure I speak for the other members of the committee who find themselves in the same position.

Do you have any questions, Mr. Rhodes?

Mr. RHODES. No questions.

Mr. WILLIAMS. Mr. Heselton?

Mr. HESELTON. No questions, except to express appreciation for the contribution made by Judge Biggs, as he always makes to this committee in every task that we have before us.

Judge BIGGS. Thank you, sir.
Mr. WILLIAMS. Mr. Dingell?
Mr. DINGELL. No questions. Thank you.
Mr. WILLIAMS. Dr. Neal?
Mr. NEAL. I have no questions.
Mr. WILLIAMS. Mr. Loser?
Mr. LOSER. I would like to ask just a question or two.
Judge BIGGS. Yes, sir.
Mr. LOSER. Down in my State of Tennessee we review the action of administrative boards and commissions by what we call a common law certiorari, that is, the appellate court or the court issuing the certiorari reviews the record, and if there is substantial evidence from an examination of the entire record to sustain the judgment of the board, it is made final.
Judge BIGGS. Yes, sir.
Mr. LOSER. We have no de novo trial, and I take it that in interpreting what the Chief Justice said, and reiterated by Senator Barkley, that they were referring to what we know as common law certiorari?
Judge BIGGS. That is correct, sir.
Mr. LOSER. And I get the impression that you are advocating here that in a review of the decisions of the administrator or director of this department, that it shall be done in the fashion outlined?
Judge BIGGS. That is correct.
Mr. LOSER. Thank you so much.
Judge BIGGS. That is correct, sir.
Mr. WILLIAMS. Mr. Wolverton?
Mr. WOLVERTON. Mr. Chairman, just one comment and one question.
In the first place, I note that, in speaking of the question of the burden upon the court, Mr. Austern cited 1 instance out of 11,000 cases to indicate that it does not bring a great burden.
On the other hand, you have cited one case the trial of which would bring a great burden.
I am wondering where that leaves us from the standpoint of background of experience if we are to judge each instance by one case?
Judge BIGGS. Well, of course, the Administrative Office of the United States Courts does not have any statistics on this issue because they have not been tried out in practical use; that is to say, unless you had your Declaratory Judgments Act procedure or the injunction procedure in use which are advocated in the first three bills that I mentioned, declaratory judgments in respect to Mr. O'Hara's bill, and injunction procedure in respect to yours.
It is pure guess, and it may be that Mr. Austern's guess is correct that these changes would not put a greater burden on the courts.
But let us assume that you were to get out of these changes 10 cases a year. That would be some burden.
Of course, if you got a case like the Atlas case, it would be my candid opinion, having looked at that record, that it would probably take a good United States district judge, a skillful judge, an experienced judge, somewhere in the neighborhood of 8 weeks to have made that record, and probably then a considerable length of time to review it and get out an opinion with findings of fact and conclusions of law, as the Federal rules require.

But this, if you please. sir, is just one of a number of Federal agencies that we are dealing with here today. It is a very important one.

But the list of other Federal agencies is a very long one; and suppose you get maybe 10 cases a year here which, I think, is a rather conservative estimate—I am trying to put my estimate in terms of real conservatism—and you multiply that by the number of agencies which, as you know, sir, exceeds a score and a half or more, and once you get to the point where you have the United States district courts performing functions of this sort, I am certain that you will have to have additional judges.

Somewhat of an analogy is provided, I think, although, perhaps, Mr. Austern would not agree with me—and, do not misunderstand me, Mr. Chairman and gentlemen, I am not saying my judgment is better than his. I do not know this would eventuate; but, of course, as you know, the Urgent Deficiencies Act provides for a three-judge court to pass upon the record and the orders of the Interstate Commerce Commission.

Now, that is done under what is the equivalent of the certiorari process. You search the record. It is not certiorari; it can be described as a de novo action, that is, an original action brought in court, but it is not really de novo. You decide it on the record that the Interstate Commerce Commission had before it, and you search the record. Certiorari means to make the record more certain, to search the record.

We have in the third circuit, on an average of about 20 of those cases a year. We pass on the questions of law presented by the record prepared by the Interstate Commerce Commission, which are frequently very long records. In fact, a short one is rather an exception.

It would be my guess that you would have a good many more cases a year involving the Secretary's decisions and if you got trials de novo under this procedure started and the courts would have a very heavy burden indeed.

I could not tell you how many cases there would be, and I do not know how you would find out, but it would be my guess that in view—let me put it bluntly—in view of the present dissatisfaction which is expressed in regard to the decisions of the Secretary, in regard to additives, there would be a lot of these cases which would come into the United States district courts.

Mr. WOLVERTON. Well, I can very well understand the merit of what you have said with respect to the burden that it may place on the court.

Yet I am aware of the fact that there is a fundamental question there that seems to me may not be fully taken care of by the procedure that you speak of in the nature of a certiorari proceeding.

If I understood the question that was asked by Mr. Loser, and your answer, it would seem that if an examination of the record showed any basis for the decision of the administrative agency, that that would be sufficient to uphold the action that was taken.

Now, if I am correct in that understanding, it would seem to me that in view of the fact that the Administration prepares the case that goes up to the court, as indicated by Mr. Austern, that then it would seem as if they have an advantage in presenting the matter.

I am wondering if there might be any in-between procedure——

Judge BIGGS. Pardon me, sir?

Mr. WOLVERTON. Instead of a trial de novo—and right there I may say that although it may appear in the bill that I have introduced, yet I am aware of the fact that these matters are so fundamental that they do require a very considerable study, which does not necessarily mean that I would be in favor of that under any circumstances whatsoever, and especially when we have the benefit of testimony such as yours, and testimony that Judge Stephens has given on other occasions before this committee, and we certainly must take into consideration what you men, learned in the law, of practical experience in the courts have to tell us, based on your experience—

But I had this in mind: Is there any in-between ground that might commend itself? If my understanding is right the present rule is that if there is anything in the record to justify the decision, the action of the administrative agency is then upheld. Instead of trying the case de novo the court might base its opinion on the entire evidence, and might determine whether it would come to the same conclusion that the Administration did on all of the evidence that was presented—that is, the real merits of it, on the basis of the case as presented to them. Such a review, coupled with some provision that would enable a case to go to the Supreme Court, might be satisfactory to both sides in presenting the question, both from a factual and legal standpoint that each might think was necessary, rather than leaving it so entirely in the hands of the administrative agency.

Judge BIGGS. Mr. Wolverton, I would like to make one statement, and that is this:

The courts of appeals do not uphold——

Mr. WOLVERTON. It is very difficult to hear you.

Judge BIGGS. Pardon me.

The courts of appeals do not uphold an order of an administrative agency, at least they are not supposed to uphold the order of an administrative agency simply because there is some basis or any basis in the record.

You will remember that originally it was provided that if there was any evidence submitted, the courts would uphold the decision.

Later it was "substantial evidence," not hearsay, but sound legal evidence. But in recent decisions, for example, in the Universal Camera Corp. case, and such cases as *National Labor Relations Board* v. *The Pittsburgh Steamship Company*, the Supreme Court held that upon the review of the whole record, using the whole record as a basis, there had to be substantial evidence to support the finding.

Now, that does not seem to have afforded a great deal of satisfaction to the proponents of legislation.

But it is a fact that unless the whole record supports the conclusion of the administrative agency, whether it be the NLRB or the FPC or the Secretary or any other agency, the courts of appeals will set the order aside.

But that is not entirely satisfactory because of the attitude which I think most litigants who come before us show—a rather disinclination to accept the findings of the administrative agency.

They seem to lack confidence in the agency's, to put it bluntly, impartiality.

That was very noticeable in respect to NLRB cases in the early days.

Now, this problem could be solved, gentlemen, by rather drastic methods. I have some hesitancy in suggesting it. The reason that this malaise or unease is felt in respect to agency decisions—and, mind you, I am casting no aspersions on the agencies, I want to make that perfectly clear, for I think their decisions are just and carefully reasoned and skillful—is that they are made by the agencies which, of course, act, in a sense, as prosecuting officers and also as judges.

Now, there have been many steps taken to ameliorate that condition. Many agencies keep, for example, their prosecuting staff members apart from their deciding staff members and the individuals who decide cases—here, for example, the Secretary is in a position which is really neutral, but that fact does not appear with sufficient clarity to satisfy the popular demand. Many people do not realize that.

The solution would be, of course, to create a deciding body which had no connection with the agency, and then you would have a quasi-judicial tribunal or a tribunal making quasi-judicial decisions, which, in effect, and which, in fact, would have no connection with the agency itself. That is the only way that you can do it.

The only other way, of course, would be to put the deciding factor in the United States district courts and have these de novo hearings, and there I have expressed myself so fully I do not need to say anything more.

But, for example, if you had for this agency a group of individuals selected by the President, and they sat and heard these cases and were not connected with the agency, I think you might obliterate a great deal of the opposition which exists in respect to agencies and agency decisions.

As I say, what I say is not intended, Mr. Chairman and gentlemen, to reflect on agency decisions.

What I say is based more on an attitude of public mind and the mind of the manufacturer, for example, such as Atlas, who—I do not use Atlas as an example, because I do not think Atlas ever claimed the agency deciding its additive case was not fair. It simply thought it was misguided, did not understand what it was talking about, or that maybe it had a certain set in a certain direction.

You could solve this problem in the way I have suggested, and that is the other way to do it, I am afraid, and, of course, this would mean setting up a new quasi-judicial tribunal, and perhaps that is what should be done.

Of course, you could do it, also, though perhaps not as effectively, by a revision of the Administrative Procedure Act, which has long been contemplated, and which, frankly, gentlemen, does need revision. I think everybody would agree on that.

Mr. WOLVERTON. Well, we appreciate having your testimony.

Judge BIGGS. I am sorry to have taken so long. I have gone way over my time, and you have been very courteous in hearing me.

Mr. WOLVERTON. We appreciate having your testimony with respect to this matter you have brought to our attention.

It would seem to me that it might be possible—and maybe this is a case of hope springing eternal—but it would seem to me from the cases you have cited in the Supreme Court that the Court seems to have enlarged the viewpoint expressed in the questions Mr. Loser asked

and the answers given, and that there might be some language that could be used that would insure, to the satisfaction of litigants as well as to the administrative departments, this full presentation to a court on appeal without a full trial de novo; and if that point that I have made has appeal with the committee, of course, we can then pursue our thought along that line that you have suggested by reference to those Supreme Court decisions.

Judge BIGGS. Mr. Chairman, could I say one thing more? I want to make plain that my statements about how this matter should possibly be handled, my latter statements, are my own views and do not represent those of the Judicial Conference of the United States.

Mr. WILLIAMS. I was going to ask you that question.

Judge BIGGS. I want to make that quite clear.

Could I say one other thing?

Of course, in *Morgan* v. *Daniels*, where you have an appeal from the United States Patent Office, you do have a sort of hybrid proceeding, in which the record, the file-wrapper history made in the Patent Office, is part of the record, and then you have the right to take testimony in a United States district court. That is *Morgan* v. *Daniels;* I do not remember the Supreme Court citation.

That is a hybrid proceeding, and I call that to your attention, gentlemen, not because I think it necessarily desirable, but it is along the lines that you have just suggested, Mr. Wolverton.

Mr. WOLVERTON. Mr. Chairman, I have no further questions, but I do want to express appreciation for the appearance of Judge Biggs before us.

Of course, those of us who live in the vicinity of the locality in which the judge acts are thoroughly familiar with the fine record that he and his court have made, and it takes on an additional importance to us when he comes and expresses his opinion to this committee.

I wanted the members of the committee to know the high regard in which Judge Biggs and his opinions are held in our local district.

Judge BIGGS. Thank you, sir.

Mr. WILLIAMS. Mr. Dingell indicated that he wanted to ask a question.

Mr. O'HARA. I would like to ask a couple of questions.

Mr. WILLIAMS. Would you mind if Mr. Dingell asks his questions first?

Mr. DINGELL. Just very briefly.

Judge BIGGS. Yes, Mr. Dingell.

Mr. DINGELL. Judge, am I to infer from your statement that you feel that a substantially fair and substantially just determination could be made on almost if not all cases under the existing Administrative Procedure Act which would be applied to review of findings of the Food and Drug Administration under H. R. 6747 and other similar bills?

Judge BIGGS. Well, I do not want to go too far.

It would seem to me, and again I am speaking for myself and not for the Judicial Conference, that that might afford a way out of this dilemma which seems to confront the committee and the Congress and the manufacturers.

Mr. DINGELL. But the point I would like to button up, if I could, Judge, is this:

It would be more or less fair to say or just to say that a fair result and a just result is usually reached under the Administrative Procedure Act, where you have the review of the record to determine whether or not it——

Judge BIGGS. Yes. What I meant to say was where the Administrative Procedure Act now reaches, I think it is a fair and adequate review.

Mr. DINGELL. Particularly in view of the finding of the court in this recent Camera case.

Judge BIGGS. Yes.

In view of those cases which I can give the citations of, the *Universal Camera* v. *National Labor Relations Board*, and *National Labor Relations Board* v. *The Pittsburgh Steamship Company*, and the first one is 340th United States Reports, page 474, and the other one is 340th United States Reports, page 498.

Mr. DINGELL. The point I was particularly interested in, and I wanted to get your views on, is the charge that has been made, or at least the inference has been made in this committee, that it is often not possible to reach a just result under the Administrative Procedure Act, and I wanted to see whether or not you would agree with that.

Judge BIGGS. My view is that it is possible, and one does reach a just result under the Administrative Procedure Act.

Mr. DINGELL. That would be true in most cases?

Judge BIGGS. That would be true in every case I have come into contact with, and I come into contact with quite a few.

My own personal experience would indicate that what you have stated, Mr. Dingell, is entirely correct.

My statements are that an independent reviewing agency, within the administrative system, so to speak, is based not on the fact that I think that these administrative agencies hand down wrong decisions or are biased, but there seems to be a feeling among some manufacturers and some members of the public that that is the case.

Of course, there are certain revisions of the Administrative Office Act which are largely administrative, which apply to the administrative techniques within that act, which could be improved. But in substance the act does a good job.

Mr. DINGELL. Thank you very much, Judge.

Mr. WILLIAMS. Are there any further questions?

Judge, on behalf of the committee, permit me to again thank you for giving us——

Judge BIGGS. Thank you so much.

Mr. WILLIAMS (continuing). Your opinion on this matter.

It certainly is a great problem to the committee what to do about this legislation, and we are very happy to have your views.

Judge BIGGS. Thank you very much.

Mr. WILLIAMS. I submit a letter from the National Council of Farmer Cooperatives for inclusion in the record.

(The document referred to follows:)

NATIONAL COUNCIL OF FARMER COOPERATIVES,
Washington, D. C., July 11, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D. C.

DEAR MR. WILLIAMS: In the hearings scheduled to begin on July 15, covering the regulation of use of chemical additives in food products, we would urge that matters relating to the use and tolerances for pesticides used in the production and handling of raw farm products be not brought in to confuse the issue regarding chemical additives for food products.

The regulation of use and tolerances for agricultural pesticides was thoroughly explored and covered in the 1954 hearings and in the enactment of Public Law 518 (83d Cong.), the so-called Miller amendment. The law has been in effect for 3 years and has been found to be generally acceptable to consumers and producers, the chemical industry, and the Food and Drug Administration. Minor adjustments in the regulations are being made as experience is accumulated.

Public Law 518 has proven to be an excellent model for legislation to regulate a highly technical type of activity such as this, in the interest of all concerned.

Sincerely yours,

JOHN J. RIGGLE, *Secretary.*

Mr. WILLIAMS. The committee will stand adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 12 noon, the subcommittee recessed, to reconvene at 10 a. m., Tuesday, July 23, 1957.)

FOOD ADDITIVES

TUESDAY, JULY 23, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334 New House Office Building, Hon. Martin Dies presiding.

Mr. DIES. Our first witness this morning is Mr. Howard O. Hunter, of the American Institute of Baking.

You may proceed, Mr. Hunter.

STATEMENT OF HOWARD O. HUNTER, PRESIDENT, AMERICAN INSTITUTE OF BAKING, CHICAGO, ILL.

Mr. HUNTER. Mr. Chairman, my name is Howard O. Hunter. I am president of the American Institute of Baking, located in Chicago, Ill. I am appearing before you today in support of H. R. 366, and most of the sections of H. R. 6747, for the purpose of amending the Food, Drug, and Cosmetic Act so as to provide additional safeguards to the use of new additives to food.

I have had the privilege for over 5 years of serving as a rather informal chairman of a group representing major food industry associations which has had over 40 meetings since 1952 on the subject of the safety of new additives proposed for use in food.

The food-processing industries have been greatly concerned over the question of public safety involved in adding new materials to our products. We have felt that the present Food, Drug, and Cosmetic Act does not provide for the insurance of such safety.

In this food-industry group, we decided to develop a statement of basic principles which could be agreed upon, and which could then be translated into an adequate amendment to the Food, Drug, and Cosmetic Act.

In 1952, the American Institute of Baking and the American Bakers Association unanimously adopted the following statement of principles:

1. We believe it is the responsibility of the food industries to exert every effort toward the production and distribution of foods which are wholesome and nutritious and to assure adequate safeguards against contamination or adulteration which would render human food unwholesome.

2. We believe the food industries should continue to improve their food products from the standpoint of nutritive value, wholesomeness, palatability, and convenience, but in so doing public health and welfare should continue to be the first consideration.

3. We believe every substance not represented by long usage in human diet should be subject to question as an ingredient in food, and that this question should be resolved by adequate animal experimentation to prove that its use in food does not preset a hazard to public health.

4. We believe every new substance proposed for use in human food should be subjected to adequate pretesting by the manufacturer or user of the substance and that such pretesting should be required by law.

5. We believe it to be a proper function of Government to control those factors which may affect adversely public health. Therefore, we believe the results of animal experimentation in pretesting new substances proposed for use in food should be reviewed and approved by the Food and Drug Administration before the substance is allowed to be used in food sold to the public.

6. We believe the Food, Drug, and Cosmetic Act of 1938, as amended to date, does not provide adequate authority for the Food and Drug Administration to control the addition of unusual substances to those foods on which standards and definitions have not yet been promulgated, and that the law should be modified properly in this respect.

Last year, in February 1956, in hearings before this subcommittee, copies of resolutions similar to the above were inserted in the record by the American Bakers Association, the American Farm Bureau Federation, the American Meat Institute, the Dairy Industry Committee, the Institute of Shortening and Edible Oils, the Millers' National Federation, and the National Restaurant Association.

There are some differences of opinion between the food industries and the Food and Drug Administration as to certain technicalities in the proposed legislation.

But the important fact is that there seems to be a unanimous agreement that these two basic principles should be incorporated into the law, namily: (1) That the manufacturer or user of any new additive to food shall adequately pretest such additive for its safety in human consumption; and (2) that the results of this pretesting shall be approved by the Food and Drug Administration before the new additive is allowed to be used in, or on, food.

The present Food and Drug Act does not provide for such pretesting, or prior approval. The present act does not permit the Food and Drug Administration to prevent the use of a new chemical additive to unstandardized food until the Food and Drug Administration can prove it is poisonous or deleterious after it has been used.

No doubt there was a time when this point was not as serious as it is now, or might be in the future, but the great advances in chemistry seem to us to make it advisable that we now place safeguards against the use of untested additives to food.

There is no emergency in our food supply which would warrant the hasty introduction of any new chemical additive.

The Congress, in amending the Food and Drug Act in 1938, recognized the same principles we are advocating by changing the drug section of the act to require adequate pretesting and prior approval by the Food and Drug Administration before a new drug could be introduced to the public.

I can assure you, sir, that if anything happens to a food due to a chemical additive which causes trouble to the consumer, that it will not be the manufacturer of the additive who gets blamed, but it will be the processor of the food.

We, therefore, are concerned not only for the consumer but for our own food industries as well.

I wish to say emphatically, and I think on this point I can speak for all of us in the food industries, that our food supply in this country is good—and it is safe. We undoubtedly are the best fed nation the world has ever known.

It is possibly true that too many people are not properly nourished, but this is largely due to food faddists and diet crackpots who have led some people to believe in all kinds of reducing diets and phony health foods.

There is ample and adequately nourishing food for the entire population of this country if people would learn to eat this food in the proper balance.

It is disturbing to note the activities of food faddists, both individual and organizations, in trying to mislead the consumer as to our food supply. Some of these faddists are, no doubt, sincere, but many of them are not.

Many of them have special diets, and so-called health foods, which they sell to the consumer. Worse than that, many of these quacks operate on a technique of fright, and try to scare the wits out of the consuming public as to our food supply.

The chemical industry has helped to make our food supply more adequate and more nourishing. We certainly would not have had as good a food supply within the reach of our entire population except for the use of chemicals in agriculture and in the processing of agricultural products into food, and there is going to be a continuing need for the development of new chemicals for use in our food supply.

We are most anxious that there continue to be research and development in the production of useful additives to food, and we believe that H. R. 366 would in no way handicap such research.

We do feel very strongly, however, that for the protection of the manufacturer, the food processor, and the consumer, the Congress should provide more adequate safeguards to the introduction of new additives to our food supply.

We wish to call the committee's attention to the somewhat unusual fact that practically an entire industry has joined in requesting the Congress to put these safeguards into legislation which affects their own industry.

In other words, we in the food industries have initiated and given momentum to this proposal for a food additive amendment to the present act. It certainly has not been forced upon us, and I am sure that the record will show that the leadership in securing hearings before you gentlemen on this subject has come from the food industries.

I close my statement on behalf of the American Institute of Baking urging upon you gentlemen the passage of an adequate amendment to the Food and Drug Act which would incorporate the basic principles which I have enumerated.

Thank you very much, Mr. Chairman.

Mr. DIES. We thank you for your statement.

Mr. Dingell, do you have any questions?

Mr. DINGELL. No questions, Mr. Chairman.

Mr. DIES. Mr. Carrigg?

Mr. CARRIGG. No questions.

Mr. DIES. Mr. Loser? Mr. Wolverton? Mr. O'Hara?

Mr. O'HARA. Mr. Hunter, I presume one commodity that everybody eats are the products you sell. I say I assume that everybody eats bread.

Mr. HUNTER. I would hope so.

Mr. O'HARA. In varying degrees, I assume.

I do want to compliment you on the attitude that has been expressed by you and the approach by your industry to this problem.

The practical view of it, as I take from your statement, is that you feel there is need for legislation, that it should be sound, constructive and sensible in its approach to this problem, and not hysterical; is that correct?

Mr. HUNTER. Yes, sir.

Mr. O'HARA. That is all I have, Mr. Chairman.

Mr. HUNTER. I have been disturbed, Mr. O'Hara, considerably, as I have indicated in here, over the last several years, by magazine articles, newspaper articles, columnists and radio announcers trying to scare the public into thinking there is something wrong with our food supply.

We do not think there is, but we do think we would like to be protected, both as to the industry and the consumer, from anything that might happen in the future.

Mr. O'HARA. Thank you.

Mr. DIES. Thank you very much.

Mr. HUNTER. Thank you, Mr. Chairman.

Mr. WILLIAMS (presiding). Mr. George Faunce, representing the American Bakers Association.

STATEMENT OF GEORGE FAUNCE, JR., ON BEHALF OF THE AMERICAN BAKERS ASSOCIATION

Mr. FAUNCE. My name is George Faunce, Jr. I am vice president and general counsel of the Continental Baking Co. with home offices in Rye, N. Y.

I am testifying this morning as a member of the National Affairs Committee of the American Bakers Association and as a member of its board of governors.

The American Bakers Association, as indicated by Mr. Hunter, subscribes to the statement of principles on food additives which he read to your committee.

The baking industry, in cooperation with other food industries, has worked toward translating these principles into a workable amendment to the Federal Food, Drug, and Cosmetic Act, for approximately 5 years.

As this committee knows from the testimony introduced on the several bills before it last year, there have been, and still are, many proposals and suggested ways of accomplishing this end.

In our testimony we will generally confine our observations to two principal bills, H. R. 6747, introduced by Chairman Harris, and H. R. 366, introduced by Representative O'Hara.

The development of a satisfactory bill on this complex subject has had as tortuous a course as perhaps any other major piece of legislation. We do not consider that unfortunate, for it has focused attention on some phases of this legislation which might otherwise have been ignored.

In the development of this legislation there have been many varied viewpoints as to the best approach to the common objective. Although all of these have not been entirely resolved, several of the differences which existed have been reconciled. The differences among various bills are concerned more with the best approach to the problem rather than with questioning the need.

The baking industry, which provides consumers with close to $5 billion worth of products annually, supports this legislation because it believes it will assist it in fulfilling its obligation to provide the consuming public with nutritious and healthful products.

Many new and excellent developments in food have been made possible by research in chemicals. Our industry, as do other food industries, wishes to take full advantage of these developments.

On the other hand, it is impossible for the average baker to evaluate many of them with respect to their safety. As to their function, a little experience in their use can soon demonstrate whether they have a functional value or are economically desirable. The baker needs no Government agency or any legislation to guide him on that score.

But as to the safety of the product, that is a scientific problem which is beyond him. The chemical companies do a splendid job in checking all their ingredients; it would indeed be an exceptional case should a baker receive an ingredient from a reputable chemical company which had not been adequately tested for its safety.

But this is an area which is affected with a public interest, and the public health should be afforded every safeguard.

We believe this can be done, and we are hopeful that the legislation which will ultimately be enacted will accomplish this, by combining maximum safeguards for public health with minimum surrender of economic freedoms and without discouraging continued scientific progress in nutrition and in food technology to promote greater variety and wider distribution of foods to the consuming public.

In our considered judgment, of all the bills before this committee on this subject, the one which will most effectively accomplish the objectives sought, provide adequate protection from possible administrative abuse, and be simplest in procedural techniques, is H. R. 366.

We know, however, that the provisions in that bill providing for the use of the declaratory judgment appeals procedure are unacceptable to the Food and Drug Administration. Although we do not consider their objections to be well-founded, nonetheless, this committee may conclude that the administrative procedure in H. R. 6747 is preferable.

If so, we strongly urge that the weight of the evidence rule be required rather than the substantial evidence rule. This will be discussed in more detail later in my statement.

May I observe, before getting into a detailed discussion of the proposed amendment on "chemical additives," that we consider a more descriptive and proper term to be "food additive." I would suggest that in the final legislation the term "food additive" be substituted for "chemical additive."

Turning now to the bills H. R. 366 and H. R. 6747, our views could perhaps be summarized, first, by saying that the question of functional value of an ingredient has no place in a bill dealing with toxicity of food.

Second, a real and substantial appeals procedure should be available to protect the individual rights of all applicants.

Third, the definition of "food additive" should be specific as it is in the O'Hara bill, to establish a definitive guidepost for the Secretary.

Referring first to the definition of "food additive," in our opinion the definition in H. R. 366 is precise and does not attempt to embrace all areas, as does the definition in H. R. 6747.

Also, H. R. 6747 does not contain a definition of the terms "safe for use" or "conditions of its intended use." H. R. 366 does define these terms, and we would recommend that these definitions be incorporated into the final legislation. We have attached the suggested language in exhibit A, which is the same language appearing in the definitions in H. R. 366.

(The document referred to is as follows:)

EXHIBIT A

"(s) The term 'new food additive' means any substance used or intended to be used for any purpose in the manufacture, packing, processing, preparation, or or other fabrication of any food, or in the packaging, transporting, or holding of it, which (1) thus becomes or could reasonably be expected to become a component of such food and (2) is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of food, to be safe for use under the conditions of such use or intended use. The term does not include a pesticide chemical in or on a raw agricultural commodity; or, with respect to a particular food or class of foods, any substance to the extent to which its use for general consumption in the United States in or on such food or class of foods is authorized or approved by the Food and Drug Administration or the Meat Inspection Branch of the United States Department of Agriculture, or any substance to the extent to which its use in or on a food is approved by or under this act. Each new food additive shall be deemed a food, for the purposes of this act.

"(t) The term 'safe for use' when used with reference to a new food additive shall mean that it is reasonably probable that such new food additive can be used under the conditions of its intended use without rendering the food in or on which it is used injurious to health.

"(u) The term 'conditions of its intended use' when used with reference to a new food additive includes, but shall not be limited to, specifications as to the particular food or class of foods in or on which said additive is intended to be used, the quantity intended to be used in or on such food, and the manner in which said additive is intended to be added to or used in or on each such food."

Mr. FAUNCE. We are opposed to having the Food and Drug Administration determine whether or not a proposed new food additive has any functional value. If the Secretary, upon examination of a proposed new food additive, finds that it is without hazard to the health of man or other animal, the question of what its function is should be of no concern to him. That is an economic determination which is the prerogative of the potential user.

Nor should the functional value of a proposed new food additive be a relevant factor to be used by the Secretary in arriving at his determination. In other words, the question of functional value should not be injected at all in a bill concerned solely with the safety of an additive.

We believe, too, that it is necessary that users of chemicals, and manufacturers should know as soon as possible after the passage of this amendment whether the Secretary considers any particular additive in use at the time of its passage to be a "new food additive" within the meaning of the amendment.

To meet the problem, we would like to submit language as set forth in exhibit B to our statement.

(The document referred to is as follows:)

EXHIBIT B

2. STATUS OF CHEMICALS PRESENTLY USED

Add a new paragraph to subsection 409 (a) of H. R. 6747 or 409 (h) in H. R. 366 reading as follows:

"409 (a) (3). Upon written request, the Secretary shall advise interested persons whether he considers a substance to be a chemical additive as defined in section 201 (s). Such written request may be accompanied by data upon which the interested person relies to establish that the substance is one that is generally recognized as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use. If the Secretary concludes that the substance is a chemical additive as defined in section 201 (s), he shall give the reasons for his conclusion. Any person who will be adversely affected by such conclusion, may file objections specifying with particularity why he believes the conclusion is erroneous and requesting a public hearing on his objections. Thereupon, the Secretary shall, after due notice, hold a public hearing for the purpose of receiving evidence relevant and material to the issues raised by the objections. As soon as practicable after completion of the hearing, the Secretary shall act on the objections and shall by published order state whether or not the substance is a chemical additive as defined in section 201 (s). Such order may be judicially reviewed under section 409 (h)."

Mr. FAUNCE. Perhaps the only substantial area of disagreement continuing to exist between us and the Food and Drug Administration concerns itself with the appeals procedure from an adverse decision of the Secretary to which I earlier referred.

Our industry, from long experience with the Food and Drug Administration, has the highest regard for its personnel and the manner in which the Food and Drug Act has been administered. However, we are very conscious of the fact that a law such as this, once passed by the Congress, becomes a permanent thing. At some day in the future, we may not have an administration which is as impartial and understanding as in the past.

Considering the fundamental thesis that ours is a Government of laws, not of men, and is based on a separation of powers, we consider it imperative that there be provided adequate judicial remedy to an applicant who believes he has not had a fair determination by an administrative agency.

In the past few years, those of us who have worked with this problem have considered many approaches for this purpose. One has been to authorize injunctive proceedings, an approach, incidentally, which is included in H. R. 8390 and H. R. 8629, discussed so thoroughly yesterday by Mr. Austern.

H. R. 366 embodies what we consider the preferable procedure; namely, authorizing the seeking of a declaratory judgment. The Food and Drug Administration has indicated its determined opposition to the use of either approach. Their views are contained in the hearings of last year.

The presentation in support of this procedure by Mr. Glenn Paxton last year, testifying in behalf of several food industries, including ours, is similarly recorded there, and it seems unnecessary to say more at this time than to reaffirm all the points so ably made by him.

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In the interest of reaching an accord and assisting in the passage of this needed legislation, we have been willing to modify previous proposals to accept the administrative procedure urged by the Food and Drug Administration and embodied in H. R. 6747, provided that in the event of an appeal to the courts, the Secretary's findings of fact shall be conclusive only if supported by the preponderance of the evidence. This we consider the minimum acceptable appeals provision to protect the rights of an individual on appeal.

It is our understanding that the Food and Drug Administration is not willing to consider favorably even this moderate appeals procedure, but insists on the so-called substantial evidence rule which would make conclusive factual findings by the Secretary when supported by substantial evidence on the record as a whole.

We submit that such an approach gives an illusory right of appeal from an adverse decision of the Secretary. Certainly it is not consistent with our concept of providing an adequate judicial remedy upon appeal from administrative determinations.

Although it will unquestionably be argued that it is consistent with the Administrative Procedure Act and that such act should not be changed by way of amendment to the Food and Drug Act, it does not seem to us that this is truly a sound argument against giving an applicant an opportunity to have his day in court with a true judicial determination as to the sufficiency of the findings of the Secretary.

There are no involved questions of law in toxicity. Hence, a finding of fact which is required to be supported only by any substantial evidence clearly removes the judicial protection which should be available to an applicant.

We further submit that if industry is willing to come voluntarily before Congress and seek the controls embodied in this legislation, that the Congress should make available adequate judicial safeguards to protect it from potential abuses which can flow from the administration of this amendment.

We will be more than happy to work with the committee staff in trying to perfect this legislation, since we are desirous of having a bill which will meet the public need and accomplish the basic objectives of protecting the consumer, the food processor and manufacturer.

In conclusion, we wish to express our thanks to the committee for making this time available to us, and express the hope that whatever bill the committee in its wisdom reports, that it will be recognized as another milestone in the cooperative efforts between Government and industry in protecting and improving the public health and safety.

Mr. WILLIAMS. Does that conclude your statement?

Mr. FAUNCE. Yes; it does.

Mr. WILLIAMS. Do you have any questions, Mr. Dies?

Mr. DIES. No questions.

Mr. WILLIAMS. Mr. Carrigg?

Mr. CARRIGG. Mr. Chairman, I would like to compliment both Mr. Faunce and Mr. Hunter upon a very splendid presentation.

I believe that you are on sound legal ground when you talk about this method of procedure involving the declaratory judgment rather than the injunction.

I wonder if there would be some way in which your industry could get together with the Food and Drug Administration and work out some changes in the proposed legislation which would be acceptable to both the Food and Drug Administration and yourself?

The reason I say that is that I have great admiration and respect for Mr. Larrick, who is the Administrator of the Food and Drug Administration, and I believe he is about as fairminded an individual as you will deal with in this particular type of question. And it is for that reason that I make the suggestion that perhaps there might be some middle ground upon which you could meet and work out legislation which would be beneficial to the consumer, and at the same time be helpful to the processor or baker.

Do you think that could be done?

Mr. FAUNCE. I think I have suggested that on page 4 of my statement, in which we said that in the interest of passing legislation, we would be willing to accept a "preponderance of evidence" rule on appeal to the circuit courts of appeal. Even though we think basically the declaratory judgment is the soundest and fairest, nevertheless we could, in working with the Food and Drug, develop this approach.

But it is our understanding at the moment that they do not even consider that as a workable approach.

It may be developed later that they would give on that, but at present, that is our understanding.

Mr. CARRIGG. When you speak about the functional value of these additives, it is your idea that that should be determined more by the consumer than by the Food and Drug Administration?

Mr. FAUNCE. The consumer, and the baker, the person who makes it. He thinks it has a value that will do good to his business and he will sell the product. That is an economic business determination which should not be regulated or regimented, particularly by the Food and Drug Administration, which is primarily concerned, as I see it, at least, in protecting the public from adulteration and poisonous, toxic substances.

I think when they have done that job, they have done a tremendous job and should not get over into the other field.

Mr. CARRIGG. I am wondering about these different types of bread that we see on the market now, particularly in view of the statement that was made by Mr. Hunter about these people who are diet faddists.

I am a little vulnerable to that, myself, I guess. But is it true that the advertising, the public relations that have been entered into between the baker and the consumer, perhaps is a little misleading at times?

Mr. FAUNCE. I do not think so.

Mr. CARRIGG. You do not?

Mr. FAUNCE. I think a lot of people in some of the bureaus believe so, and then we have to sit down with them and talk to them and explain. Once in a long time, we have a real dispute.

Mr. CARRIGG. What I am trying to get at, in other words, is it a fact that very often when you advertise a certain bread has certain functional values, that perhaps it does become necessary for the Food and Drug Administration to take a look at that particular bread and determine for itself whether it has or not?

Mr. FAUNCE. Are you thinking, perhaps—it is already in the main statute, the regulation of foods when they purport to be for special dietary purposes.

Now, that you might consider as a part of a functional point.

What we mean by "functional," is that we do not want the Food and Drug to say that this item, new food additive, cannot be used for a certain purpose in the product, when the determination will be whether the public accepts it and it can be sold and consumed, assuming that it is safe.

Mr. CARRIGG. Well, I again say that I think you are about as fair a group of individuals as any who have come before this committee in your attempt to cooperate with the committee in the proposed legislation, and I think that perhaps if you could sit down for just a while longer with the Food and Drug Administration, you could come up with a bill which would be very acceptable to everyone.

Mr. FAUNCE. We certainly will never stop trying to do that.

Mr. CARRIGG. I will urge that upon Mr. Larrick.

Mr. FAUNCE. Thank you, sir.

Mr. CARRIGG. That is all.

Mr. WILLIAMS. Dr. Neal?

Mr. NEAL. No questions.

Mr. WILLIAMS. Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. Faunce, I was very much interested in your position that the Food and Drug Administration should not be permitted to inquire into the usefulness or the functional value of a food or chemical additive.

Let me ask you this question about that, if I may: Do you think that chemicals and additives should be added to foods of various kinds which have no functional value?

Mr. FAUNCE. If they are not harmful to the consumer, that is the business of the producer.

Mr. DINGELL. Will you illustrate one additive which should be added or which could properly be added to foods which has no functional value?

Mr. FAUNCE. No, I cannot at this moment. I am not in the manufacturing end of our business. I cannot at the moment think of one.

Mr. DINGELL. Well, could you illustrate, perhaps, a purpose for which some useless chemical or useless substance should be added to the food?

Mr. FAUNCE. A substance is not useless if, assuming its safety, it is used in a product and the product is improved, and it improves its sale. You cannot tell, I do not see how you can say it was a useless product.

Mr. DINGELL. Are you not begging my question? And are you not having to answer my question, when you do that, should you not say there that if an article or a chemical or chemical substance has no value, it should not be added? Is that not a fair statement?

Mr. FAUNCE. It has no value of what kind?

Mr. DINGELL. Has no functional value.

Mr. FAUNCE. It may be perfectly foolish for the man to add it, the manufacturer.

Mr. DINGELL. Is that not a true statement, now? Should a substance which has no functional value be added to food?

Mr. FAUNCE. It should be the determination of the manufacturer, and no business of the Food and Drug Administration.

Mr. DINGELL. All right.

But should not a useless substance not be added to food? Is that a fair statement, or not?

Mr. FAUNCE. Your use of the term "useless,' 'that confuses me. If it is useless, the man who makes it is not going to spend his money and put it in, I would think.

Mr. DINGELL. Let us get right down to this business. I want a "yes" or "no" answer. I think I am entitled to it.

Let us just take a substance which has no functional value, has no food value. It does not affect the color or the taste or salability or the preservative value of the food. Now, should that substance be added to food?

Mr. FAUNCE. If the—yes, if the manufacturer wants to add it, he should add it.

Mr. DINGELL. Then you are telling me that a manufacturer should have a blank check to add any substance he wants, as long as it is not harmful; is that right?

Mr. FAUNCE. That is right.

Mr. DINGELL. Is that right?

Mr. FAUNCE. That is my position.

Mr. DINGELL. Let us take this situation. You will agree with me that it is impossible to really know what the effect of any chemical is going to be on food, am I correct, when it is added?

Mr. FAUNCE. That is why we are going to have pretesting.

Mr. DINGELL. Yes. But even with pretesting, there are situations which can and could conceivably arise, and which have arisen in the past, in your industry, where a substance previously thought to be harmless later turns out to be harmful; am I correct?

Mr. FAUNCE. Are you speaking of Agene?

Mr. DINGELL. I am referring to an additive which was once a normal ordinary, every-day substance, which was added to food, to flour, I believe it was a bleach.

Mr. FAUNCE. Yes.

Mr. DINGELL. It was later discovered that this bleach had an extremely harmful effect on laboratory animals, and also human beings; am I correct?

Mr. FAUNCE. On laboratory animals.

Mr. DINGELL. What was it?

Mr. FAUNCE. Dogs. Agene, I think, was the name of the substance, nitrogen trichloride.

Mr. DINGELL. I believe that is the right term. And for a long time it was thought to be harmless; is that right?

Mr. FAUNCE. I do not know, but it must have been questioned. It was used for a long time.

Mr. DINGELL. And during the time it was used, it was thought to be harmless?

Mr. FAUNCE. That is right.

Mr. DINGELL. And later, I believe it was thought to produce insanity in laboratory animals. Am I right?

Mr. FAUNCE. I do not know the results in detail.

Mr. DINGELL. At any rate, it had harmful effects on laboratory animals.

Mr. FAUNCE. Some experiments conducted in England showed that. That is my knowledge, a very limited knowledge.

Mr. DINGELL. But it was shown to be harmful to laboratory animals?

Mr. FAUNCE. That is right.

Mr. DINGELL. But the implication would be that it would have the same bad effect or similar bad effect or equal bad effect on human beings?

Mr. FAUNCE. That is right.

Mr. DINGELL. And the evidence was sufficiently forceful to your industry that your industry withdrew it; am I right?

Mr. FAUNCE. I believe so.

Mr. DINGELL. So the point I make is, on the basis of this one example, and certainly there are others, it would be fair to infer that what at one time was thought to be a harmless substance could later be found to be a harmful substance; am I correct?

Mr. FAUNCE. That is right.

Mr. DINGELL. Then it would appear the mere addition of foreign additives—and additives are foreign substances, are they not?

Mr. FAUNCE. That is right.

Mr. DINGELL. It would be fair to infer, then, that additives which may be thought to be harmless but which have no functional value would not be necessarily in the public interest; am I correct?

Mr. FAUNCE. That is right.

Mr. DINGELL. In fact, it would be very proper to say that there is evidence to indicate that it might not be in the public interest to add these substances; am I correct?

Mr. FAUNCE. Right.

Mr. DINGELL. And it might even be further logical to say that it very well could be that there is a sufficient degree of danger that adding a foreign substance just for the purpose of adding foreign substances, even though they are thought to be harmless, might very well definitely not be in the public interest; am I correct?

Mr. FAUNCE. Yes.

Mr. DINGELL. In fact, it would be, it could conceivably be, against wise public policy to include the addition of foreign substances which are thought to be harmless but are thought to have no value; am I right?

Mr. FAUNCE. Correct.

Mr. DINGELL. On the basis of what you have told me, do you not think it would be wise to let Food and Drug determine this, along with other things they are going to determine?

Mr. FAUNCE. No; I do not, because I suggest to you a real possibility that if this act had been in effect with the "functional value" in it when Agene was first used, that the person who wanted to use it would certainly have thought, he would have thought at the time, that it had a functional value, and probably the Food and Drug would have agreed with him.

Mr. DINGELL. The Food and Drug probably would agree.

Mr. FAUNCE. The question of usefulness has no relation to safety.

Mr. DINGELL. The point I make is this: For a long time, mankind

has been eating ordinary foods without addition of any foreign substances; is that correct?

Mr. FAUNCE. That is right.

Mr. DINGELL. And eating these foods without added foreign substances has certainly not had the impact on the human race that the eating of foods with this added foreign substance would have; am I correct?

Mr. FAUNCE. Right.

Mr. DINGELL. So, then, the inference is clear that we can say, by and large, for many centuries the human race has gotten along without these things, and if these things serve no useful purpose, there is no reason for adding them and they should not be added; am I correct?

Mr. FAUNCE. You do not suggest that the nutritive value of food generally in this country and in the world has not generally improved enormously over the period?

Mr. DINGELL. I do not suggest anything like that. I just asked for an answer to my question.

Mr. FAUNCE. Would you repeat it, please?

Mr. DINGELL. My question is this: For centuries, the human race has gotten along without additives into foods. Let us sort these additives down into those which serve a useful purpose and those which do not serve a useful purpose, and let us just say that we can infer reasonably that the human race has probably gotten along better without the addition of useless food additives, am I correct?

Mr. FAUNCE. Right.

Mr. DINGELL. And get along very nicely and very comfortably.

Mr. FAUNCE. Yes.

Mr. DINGELL. Then can you just cite for me one benefit to your industry which would be conferred by the addition of useless food additives, additives which have no functional value?

Mr. FAUNCE. There may be no benefit to anything that is useless and safe, but I still say it is not the function of a Government bureau to tell a manufacturer of food, under our system, what he can use, if it is not harmful. We are opposed to encroachment of the administrative groups into that field. We do not think they belong there.

Mr. DINGELL. You conceded to me, and I believe in your statement you said, there is a broad question of public policy here, and the industry is affected by the public interest. Am I right?

Mr. FAUNCE. Right; as to safety.

Mr. DINGELL. I beg your pardon?

Mr. FAUNCE. As to safety.

Mr. DINGELL. As to safety?

Mr. FAUNCE. To the people.

Mr. DINGELL. And you have conceded there are a number of instances where substances previously thought to be safe had later been determined to be very much unsafe.

Now, will you name for me just one instance of a food additive or chemical or some additive substance which serves no useful value but which is safe, which would be good to add to the food supply of this country, for the consumer?

Mr. FAUNCE. No, I cannot, but I still disagree with you basically as to who is to determine whether it is useful or useless. We think we should determine it.

Mr. DINGELL. On the basis of your own own argument, who is to determine the safety? Why should the Food and Drug determine the safety and not determine the functional value?

Mr. FAUNCE. Because that is a completely different question. Useful or useless is a question of a conclusion in a person's mind. The question of safety is determined by scientific tests and experiments, and all of that sort of thing. They are completely different.

Mr. DINGELL. Are you alleging you are not going to get a fair hearing before Food and Drug?

Mr. FAUNCE. We will probably get a fair hearing. But if we do not, we want a right, certainly, to appeal on the safety. And if we were to appeal, under this administrative procedure, on usefulness, we would really be in trouble.

Mr. DINGELL. Well, I do not think you and I are going to resolve this thing.

Mr. FAUNCE. I do not think so, either.

Mr. DINGELL. I think your own testimony shows you do not really have a whole lot of faith in your own arguments.

Mr. FAUNCE. Well, I do.

Mr. DINGELL. No further questions, Mr. Chairman.

Mr. WILLIAMS. Mr. Wolverton?

Mr. WOLVERTON. Mr. Chairman, I want to address myself for just a moment to the thought that was expressed by Mr. Carrigg with reference to the industry sitting down with the Food and Drug Administration across the table, and endeavoring to come to some settlement of these questions.

I think that would be a very commendable practice.

I would regret it if there was much truth in the position which you have taken, that while you have been willing to do so, there has not been the same willingness upon the part of the Food and Drug Administration to approach it in the same maner. I wish it could be otherwise.

I remember very distinctly that in another matter of some importance in this committee dealing with a regulatory body, it was just as difficult to get the particular agency to sit down with the industry as you, by experience, evidently have found to exist in this case. The chairman of the committee in that case took a very decided stand, and he just compelled them to come together. They sat at the table where you are sitting now, and did discuss these questions, as a result of the interest that the committee took in the matter in compelling them to do so.

And I am inclined to think that if that procedure is to be followed of sitting down together in an endeavor to work out a solution it will have to be under the guidance, direction, authority, and compulsion, if necessary, of the committee itself. I certainly would want to be a party to that kind of a procedure, believing that discussion very frequently does enable people with differing viewpoints to come together, and that no Federal agency has a right to hold itself so aloof that it is unwilling to discuss freely and openly these questions.

I doubt if it would be of any use, however, to hold such a conference unless it was done under the direction and supervision of this committee, or the chairman of the committee, with the chairman acting either as an umpire or otherwise, to make certain that there is

that free discussion which the importance of the subject is entitled to have.

I have been very much impressed with two or three statements you have made in your statement, and I want to join with the others who have complimented you and Mr. Hunter upon the presentation that has been made this morning. It is characteristic of the kind of a statement that a businessman might be expected to present, in that it has been plain and it has been to the point, and it is perfectly understandable where you stand, and that is very helpful to the committee in considering this matter.

For instance, you have said:

We consider it imperative that there be provided an adequate judicial remedy to an applicant who believes he has not had a fair determination by an administrative agency.

Certainly I cannot see how anyone could disagree with that particular statement. I think everyone is entitled to have a fair determination by the administrative agency; and if he is of the opinion that such has not been the case, then I think it is only characteristic of American justice that he should be given that opportunity.

In that respect, you went on further to say:

In the past few years those of us who have worked with this problem have considered many approaches for this purpose. One has been to authorize injunctive proceedings. Another has been by authorizing the seeking of a declaratory judgment.

But the unfortunate statement which follows may be too true:

The Food and Drug Administration has indicated its determined opposition to the use of either approach.

Now, as we go down further into your statement, you have said—and I think this is very commendatory and I approve of it personally:

*** * * that in the event of an appeal to the courts, the Secretary's findings of fact shall be conclusive only if supported by the preponderance of the evidence. This we consider the minimum acceptable appeals provision to protect the rights of an individual * * *.**

I addressed myself to that thought yesterday. To me, it is inconceivable that an agency should insist, as it does, upon the so-called "substantial evidence" rule, which would indicate that if there happens to be anything in the record that would justify the conclusion that has been reached by the agency that, therefore, it must be upheld.

I think that justice requires that it should be based upon the thought that there has been a preponderance of evidence to support the findings of the agency; and, in that respect, I am inclined to believe that there is some justice or merit to the claim that when the case is presented on appeal it does not necessarily give the appellant the fair play that he should have in the matter of an appeal where the record is very largely, if not entirely, that which results from the Department itself presenting its case to the appeals court.

To my way of thinking, there should be some opportunity to make certain that the factual and other evidence which is presented to the court on appeal is comprehensive enough to include not only the agency viewpoint, but also that of the appellant, and it should not be left entirely to a matter of argument, but the basic paper on which the argument would be based can only be fair if it properly represents

the whole situation, and not one that is made up by 1 litigant or largely by 1 litigant before the court.

I probably have spoken longer than I should, Mr. Chairman, but at least I have stated my position without asking a lot of questions.

Mr. FAUNCE. On that point, we feel there is no possibility of those ever being a reversal of an adverse finding by the Secretary, because there is bound to be "substantial" evidence in every record that goes to the circuit court, by the very nature of the proceedings that have taken place in the Department; and, as I understand the Administrative Procedure Act, if there is no change from that, the appellate court must find, if there is substantial evidence, the facts in favor of the Secretary.

That is why we made——

Mr. WOLVERTON. In conclusion, I would like to say this, Mr. Chairman: that it seems very unfortunate, to me, that a department which is charged with the responsibility that this Department is, and which has done such a good job in the past in protecting the health and welfare of our people in an industry such as yours and the others that are represented here, who are likewise anxious to do only that which will prove helpful to the consuming public, both having the same objective cannot sit down and come to some private conclusion which will get the results that are desired, both by the Department and by the industry that is affected, with both working in the interests of the consumer.

Mr. WILLIAMS. Mr. Loser?

Mr. LOSER. Mr. Faunce, you are a member of the bar, are you not, a practicing lawyer?

Mr. FAUNCE. I am a member of the bar, but I am not a practicing lawyer, in the sense I am not in general practice. I am house counsel for Continental Baking Co.

Mr. LOSER. Have you ever engaged in the practice of the law?

Mr. FAUNCE. For a short period early in my career.

Mr. LOSER. Have you kept abreast of legal proceedings over the years?

Mr. FAUNCE. Generally, in reference to this bill particularly, yes.

Mr. LOSER. Are you a graduate of some law school?

Mr. FAUNCE. Yes, sir.

Mr. LOSER. What school?

Mr. FAUNCE. University of Pittsburgh Law School.

Mr. LOSER. The reason I ask you that question, I wanted to know if you were familiar with the common law, so-called, of England.

Mr. FAUNCE. In certain aspects, yes. I cannot say that I am familiar with it generally.

Mr. LOSER. You know that it is the source of all of the law of the United States other than the statutes?

Mr. FAUNCE. All the case law, yes, sir.

Mr. LOSER. And that it is source of the laws of the several States of the Union, with 1 or 2 exceptions.

Mr. FAUNCE. Yes.

Mr. LOSER. Are you familiar with what is known as common law certiorari?

Mr. FAUNCE. No.

Mr. LOSER. Well, you do know that from time immemorial, or since when the memory of man runneth not to the contrary, that there has been a proceeding, which came over here with our forefathers, adopted in all of the States, with 1 or 2 exceptions, that in matters ruled and determined by administrative agencies and boards, that a review of their proceedings is had upon the entire record, and when the administrative board has ruled, upon the examination of the entire record, that its findings are made final except for illegality or excessive jurisdiction.

Have you heard of such a rule as that?

Mr. FAUNCE. No. The Administrative Procedure Act, I am generally familiar with. Findings of fact——

Mr. LOSER. Yes, the Administrative Procedure Act; that is the course followed now——

Mr. FAUNCE. That is right.

Mr. LOSER. In Federal questions, is it not?

Mr. FAUNCE. Yes, sir.

Mr. LOSER. And if, from an examination of the entire record, a reviewing court concludes that the findings of the administrative board or agency are supported by substantial evidence, it is made final?

Mr. FAUNCE. That is right.

Mr. LOSER. Now, what is wrong with that?

Mr. FAUNCE. Well, what is wrong with it is this, as I see it: that perhaps as to the other administrations, the National Labor Relations Board, you go into an administrative proceeding there and you start fresh, both sides are putting in their views, and the staff of the Board is at least subjected to the arguments, the facts, the presentation, for the first time, pro and con.

But in this particular situation, the pretesting data and evidence has to be turned over first to the Food and Drug. Then the staff of the Food and Drug studies that and reaches a position, and if the position is adverse, then the hearing starts.

And it is not conceivable in my mind that there is going to be any change of opinion or feeling or determination on the part of that staff. Their whole evidence that they have used to support the turning down of the pretesting is going to be in that record, and it is going to be substantial evidence there that has been prejudged and predetermined before the hearings have ever started.

I think that makes a distinction.

Mr. LOSER. What you are saying is, I believe, they will act arbitrarily or capriciously.

Mr. FAUNCE. They will act to support their previous determinations in the same matter. That is human nature.

Mr. LOSER. That would be arbitrary and capricious conduct.

Mr. FAUNCE. Not necessarily. I think it is the tendency of everyone.

Mr. LOSER. You mean they would make up their mind before they actually came to a conclusion about the matter?

Mr. FAUNCE. They have to, because they will have given an adverse decision before the hearing.

Mr. LOSER. Then you just do not think you could get a fair trial?

Mr. FAUNCE. Without a review, at least, on the preponderance of the evidence, not the substantial evidence.

Mr. LOSER. Well, of course what you are saying now is that you prefer that there be a trial de novo.

Mr. FAUNCE. We think that would be the soundest way.

Mr. LOSER. And for every chemical additive that is sought to be placed in food products, that there ought to be a lawsuit going from the United States district court in a community to the Supreme Court of the United States.

Mr. FAUNCE. There should be the right to that lawsuit. It is pure speculation how frequently that would occur. Some witnesses have said that it would be frequent——

Mr. LOSER. You gave me the impression that this Food and Drug Administration would prejudge these matters, and uniformly be adverse.

Mr. FAUNCE. I did not want to give the impression that they would prejudge them capriciously or arbitrarily, but the nature of the bill requires them to prejudge before the hearing starts, and I do not conceive that those same people are going to reverse themselves within the same controversy. That is all I said.

Mr. LOSER. That would be arbitrary conduct, would it not?

Mr. FAUNCE. No. I think that is human nature.

Mr. LOSER. What you are saying is, you are attacking a rule of procedure, a rule of law, that has been uniformly adopted throughout the States of the Nation ever since its foundation, and for a thousand years across the seas.

That is all, Mr. Chairman.

Mr. WILLIAMS. Mr. Schenck?

Mr. SCHENCK. No questions.

Mr. WILLIAMS. Mr. Dollinger?

Mr. DOLLINGER. No questions.

Mr. WILLIAMS. Any further questions on the part of the committee?

(No response.)

Mr. WILLIAMS. I have one question, Mr. Faunce, and that is in regard to this matter that was brought up by Mr. Dingell on the functional value of these additives.

As I understand it, the position you take with respect to giving the Food and Drug people the right to determine the functional value is that, in effect, you are giving to the Food and Drug Administration the right to determine business policies, are you not?

Mr. FAUNCE. That is right. That is correct.

Mr. WILLIAMS. The question of the functional value of these additives has nothing whatsoever to do with the safety of those additives?

Mr. FAUNCE. Nothing.

Mr. WILLIAMS. That, I presume, has already been determined when you reach the question of determining the functional value.

Mr. FAUNCE. That is right.

Mr. WILLIAMS. And you consider that to be purely a business decision.

Mr. FAUNCE. Purely. It will be worked out in the market place.

Mr. WILLIAMS. Are there any further questions?

Mr. DIES. I should like to ask you this question:

This appeal proposition bothered us the last time. I do not think we came to any decision about it, and I do not see how you could possibly have a trial de novo on each one of these cases.

If you did, it seems to me that you would run into a great deal of difficulty there. Do you not think that?

Suppose that every time you have a decision of the administrative agency, that either they or you can go into the district court to ask for a declaratory judgment or injunction, and have a determination of it. I just do not see how that could be a very practical approach to this problem.

Mr. FAUNCE. Well, I personally, and we as a committee, think that it would be rarely invoked. And when there is an injustice, if there should be one—we do not anticipate that frequently, or that they will take place under the present administration of this law. But if it does happen, there should be that place to go so that there could be examination of the experts, their appearance, their demeanor, everything that comes out in an ordinary lawsuit which does not appear on the record that you have before the circuit court.

Mr. DIES. You see, this is quite a change from the present law. Under the present law, if you are a food manufacturer, you have to insure that your food is free from poison or will not produce deleterious results.

Mr. FAUNCE. That is right.

Mr. DIES. And the burden is really on you, the civil courts hold you to a high degree of responsibility.

Mr. FAUNCE. Very high.

Mr. DIES. And if you put something on the market, then you can be held in damages, and the Food and Drug Administration can enjoin it, and they can also hold you criminally accountable for your act.

Now you are going to approach it from the standpoint of pretesting, and that will relieve you, I would think, of some responsibility in connection with your acts, would it not?

Mr. FAUNCE. In one sense. But certainly there would be the tremendous responsibility, if you were faced with an adverse decision, a ruling by the Secretary, the tremendous decision even to go in and contest it in court, from the bad public reaction you may get from it.

So I think there would be very few instances of this declaratory judgment procedure. I think it just should be there as a safeguard.

Mr. DIES. Of course, we have this difficulty; We have an administrative act which applies to practically all of the administrative procedure in our Government.

Personally, I never have been in favor of the "substantial evidence" rule. I tried some cases, and I know that under the interpretations the courts have made, that your appeal is useless.

I do not think I recall a single case that there was a reversal, because if the court can find any evidence in the record to support the administrator—and they are going to find it, of course—the decision is upheld.

The circuit court of appeals, when you go there and argue, have got all this record to go through, and then they read the findings of the administrative agency, and that is it. There is really no appeal that I can find.

I have felt for a long time that that act ought to be amended generally as to all administrative action to protect our citizens from the interpretation that has been placed upon that "substantial evidence"

rule. I think the interpretation has done more harm than the rule itself, do you not think so?

Mr. FAUNCE. I think so.

Mr. DIES. It has been narrowed down until it is meaningless. I do not think Congress had that in mind at the beginning.

Mr. FAUNCE. That is right.

Mr. DIES. But when you come to a de novo trial, and you would have in this particular bill a de novo trial, and with respect to other administrative acts you would have the old rule. I mean, it presents a difficult problem for this committee to make an exception——

Mr. FAUNCE. That is right.

Mr. DIES. To our administrative procedure rules.

Mr. FAUNCE. Well, you could take our second line, which we said we would reluctantly agree to, the "preponderance of the evidence" rule on the administrative procedure appeal to the circuit court, and this committee might take this situation as an opportunity to pioneer in getting the Administrative Procedure Act amended through the back door by treating this situation as basically different, because it is, on the first procedure that you have to follow.

Mr. DIES. There is another question about the grandfather clause, that is, by blanketing in all these additives that have been in use.

Of course, as science progresses, it is likely that some of these additives will be discovered to be harmful.

Mr. FAUNCE. Right.

Mr. DIES. At least, they could be discovered to be harmful.

Now, in those cases, you would not want to close the door, would you? I mean, you would want to have adequate provision so that if, through subsequent tests, they are discovered to be harmful, that the same rules would apply to them which would apply to a new additive?

Mr. FAUNCE. Yes.

Mr. DIES. In those cases, should not the burden, if the administration discovers that an additive which has been in use is in fact under some suspicion, should not the burden then be placed upon the manufacturer to prove the safety of it, just as though it were a new additive?

Mr. FAUNCE. Yes, it should be.

Mr. DIES. Something ought to be written into the law, into this bill, along that line, I would think, to give the public the full protection it should have.

Mr. FAUNCE. Well, we think that our suggestion in our exhibit B, in conjunction with a provision already in H. R. 366, which says the Secretary shall publish a list, months before the effective date of the act, of the food additives, so called, that are all right, then that is going to leave a large group that are not mentioned.

Then under our suggestion, the manufacturer, the food processor, can write in as to a specified ingredient which he is using and say, "Is this to be considered safe?"

Then there will be a hearing on whether or not that was a chemical additive. If the Secretary said it was a new additive, then you would start the proceeding as though it were new.

And I think lawyers for food companies are going to have a very difficult time advising their clients as to what is and what is not subject to this law, unless there is some machinery like that set up.

Mr. DIES. Let me ask just one more question. I do not want to take up too much time.

But take this question of functional value. I can understand and appreciate the fear that if the Department can pass on that, in time the Department could substitute its judgment for the judgment of the manufacturer.

Mr. FAUNCE. Right.

Mr. DIES. But what about these cases of additives which have absolutely no functional value, that are put into food for advertising purposes. They give it the name, S. R, G, and then they advertise extensively, irium or something else.

Mr. FAUNCE. Well, I still think the manufacturer should be left free. There are other methods of catching him.

Mr. DIES. Is there any law now which would prevent, we will say, the Jones Manufacturing Co.—there is no such company, but I use that name—from using some absolutely useless ingredient solely for the purpose of deceiving the public by advertising?

Mr. FAUNCE. If it could be proved that he is deceiving the public, there are plenty of remedies on the books right now for that.

Mr. DIES. What remedies are there? Is there anyone now to test, when a manufacturer comes out with a full-page advertisement stating that they have discovered some new ingredient, that it revolutionizes this and that, is there anyone that can reach those cases of deception, of fraud?

I am not talking about where there is an honest difference of opinion as to the functional value or anything of that sort. I am talking about this: There must be some cases or instances where it is purely a fraudulent thing for the purpose of selling the product.

Mr. FAUNCE. Well, the Federal Trade Commission can reach their advertising, and the Food and Drug can reach anything they can put on the label of this product, so somebody will catch them.

Mr. DIES. That is all.

Mr. DOLLINGER. Mr. Chairman, may I ask a question of the witness?

Mr. WILLIAMS. Surely.

Mr. DOLLINGER. Mr. Faunce, you seek a de novo proceeding, not for the purpose of delay; you just want to protect your rights?

Mr. FAUNCE. Right.

Mr. DOLLINGER. By the same token, you appreciate the fact that the Food and Drug Administration is interested in protecting the health of the consumer.

Mr. FAUNCE. Right.

Mr. DOLLINGER. Would you agree that if this bill were amended to give you the right of a de novo trial, that you would consent that there should be written into this bill injunctive relief so that if Food and Drug said you could not use that substance, that you would desist from the manufacture of the product until the courts finally determine that matter?

Mr. FAUNCE. I think that is already in the bill. It cannot be used while this proceeding is pending.

Mr. DOLLINGER. Where is that in this bill?

Mr. FAUNCE. It can only be used—it is either in H. R. 6747, or H. R. 366, I think it is. It is in H. R 366.

If there is a declaratory judgment proceeding pending, you cannot. If it is not in the bill it should be.

Mr. DOLLINGER. You would subscribe to the theory——

Mr. FAUNCE. Yes, sir.

Mr. DOLLINGER (continuing). That nobody should be permitted to manufacture the product if there was a question about it, until such time as the matter had been decided?

Mr. FAUNCE. If this proceeding is adopted for appeals de novo, yes; it certainly should be. It is in the bill, as I remember it, but I will look through it again.

Mr. DINGELL. Would you agree it should be in the bill if it is not in the bill?

Mr. FAUNCE. Yes.

Mr. DOLLINGER. Yes; he does.

Mr. FAUNCE. I am informed it is in the bill.

Mr. WILLIAMS. Mr. Rhodes?

Mr. RHODES. Mr. Faunce, could you tell us what the difference is between the American Institute of Baking and the American Bakers Association?

Mr. FAUNCE. Well, the American Institute of Baking is purely a scientific, or sort of adjunct, to the American Bakers Association, in that it is largely supported financially by the American Bakers Association, but it concerns itself solely with the scientific aspects of baking and training, and runs a school, has research people; whereas the association is an ordinary trade association.

Mr. RHODES. Thank you.

Mr. WILLIAMS. Are there any further questions?

(No response.)

Mr. WILLIAMS. Mr. Faunce, the committee appreciates your appearance this morning very much. We are glad to have the views of your organization.

At this time, I submit for inclusion in the record a statement of Mr. Roy Battles, assistant to the master of the National Grange, on this legislation.

(The statement referred to is as follows:)

NATIONAL GRANGE,
Washington, D. C., July 15, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science,
United States Capitol, Washington, D. C.

DEAR CONGRESSMAN WILLIAMS: Attached you will find the statement of the National Grange prepared by my assistant, Roy Battles, relative to proposed legislation now pending before your subcommittee in the field of food additives.

I would be highly gratified if you and the members of your committee would review this statement and make it part of the record of the current hearing.

Respectfully yours,

HERSCHEL D. NEWSOM, *Master.*

STATEMENT OF ROY BATTLES, ASSISTANT TO THE MASTER OF THE NATIONAL GRANGE

In previous testimony presented by the National Grange, support was given to the enactment by Congress of legislation which would insure a sound and practical pesticide policy as was proposed in H. R. 7125, introduced by Congressman A. L. Miller. That bill became Public Law 518 of the 83d Congress, and section 408 of the Federal Food, Drug, and Cosmetic Act.

In the bills now before the committee there is considerable similarity in principle with the provisions of the Miller pesticide residue amendment. It requires that a careful and thorough pretesting be made of pesticide chemicals in order to determine their safety before being made available for use on food products. Also, that the approval of their use by the Food and Drug Administration and

the United States Department of Agriculture must be obtained before they can be used.

A practical test over a 3-year period has demonstrated the value of the legislation enacted under the Miller pesticide residue amendment to all parties engaged in the production of an adequate, safe, and wholesome food supply.

In view of the legislation now in effect under which pesticide chemicals are adequately regulated it does not seem necessary to enact new legislation affecting the continued use of pesticides.

Throughout the entire development of the pesticide program the element of safety to the consumer has received close attention, so that along with the production of an adequate food and fiber supply at low cost there has been coupled with it the assurance to the consumer that his food supply is safe from a health standpoint regardless of the methods that are used in its production.

Fortunately new types of insecticides and fungicides have been developed in rather rapid succession and are being widely used by farmers. In connection with their use and under adequate safeguards for the protection of human health over 1,200 tolerances have been set for the use of 82 different pesticide chemicals.

Members of the National Grange, both in the capacity of food and fiber producers and as large-scale consumers of both products are vitally interested in a pesticide policy that aids in the economical production of their food and fiber and at the same time insures the highest possible degree of safety to health.

We in the National Grange are especially pleased that this committee in making it possible to consider a matter that is so basically important to all citizens. We appreciate the opportunity to present our views regarding the regulation of pesticide chemicals which we believe to be adequate to protect public health.

Mr. WILLIAMS. If there are no further questions and no further business, the committee will stand adjourned until 10 o'clock tomorrow morning.

Mr. FAUNCE. We thank you very much.

(Whereupon, at 11:20 a. m., the subcommittee adjourned, to reconvene at 10 a. m., Wednesday, July 24, 1957.)

95208—58——18

FOOD ADDITIVES

WEDNESDAY, JULY 24, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334, New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. We will continue our hearings this morning on the subject of food additives, and I am pleased to recognize at this time Mr. C. C. Pearce, assistant to Hon. Usher L. Burdick, of North Dakota, our colleague in the House, who has been very much interested in this problem.

STATEMENT OF HON. USHER L. BURDICK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH DAKOTA, PRESENTED BY CHARLES C. PEARCE, OF THE STAFF OF REPRESENTATIVE BURDICK

Mr. PEARCE. Thank you, Mr. Chairman.

Mr. WILLIAMS. I believe you have a statement. You are appearing on behalf of Congressman Burdick?

Mr. PEARCE. Yes. Thank you, Mr. Chairman.

I am not going to take the time of the committee to read this statement, because I understand you are operating on a very tight schedule.

Mr. WILLIAMS. We certainly are, sir.

Mr. PEARCE. I simply wanted to identify myself as the representative of Congressman Burdick, who regrets he could not be here personally, and he asked me to respectfully submit this statement for your consideration, which deals broadly with only one question: What should be the main requirement of any amendatory legislation with respect to chemical food additives?

I believe you will see it to be his conclusion that any amendatory legislation should have a pretesting procedure as to all chemical food additives, whether carcinogenic or not.

I will conclude with thanking the committee for its consideration and indulgence in permitting us to violate your schedule, so to speak, in submitting this statement.

Thank you so much.

Mr. WILLIAMS. We are very happy to accept this statement. We regret Mr. Burdick cannot be here in person, but we are very happy

to have his statement included in the record as if it were given to the committee in person.

Mr. PEARCE. Thank you very much.

(Representative Burdick's statement is as follows:)

STATEMENT OF HON. USHER L. BURDICK WITH RESPECT TO CHEMICAL FOOD ADDITIVE LEGISLATION

Mr. Chairman and members of the committee, it is generally conceded that existing Federal statutes do not afford adequate protection to the public against the use of chemical additives in foods which may be deleterious or poisonous in their effects on human health.

The Delaney committee, which held many hearings on the subject in 1950–52, noted that most of the witnesses before it strongly recommended "that no chemical should be permitted entry into the Nation's food supply until its safety for use has been demonstrated beyond a reasonable doubt."

Dr. Harvey W. Wiley was installed as Chief of the Bureau of Chemistry of the Department of Agriculture in 1883 and held this position with great distinction until 1912. Largely through his efforts the Pure Food and Drug Act was enacted by Congress in 1906. In spite of Dr. Wiley's heroic endeavors to protect the public health against the hazards of use of poisonous or deleterious food additives, it was generally realized that, particularly with respect to adulteration of foods through poisonous or harmful substances, the 1906 pure food law needed strengthening. So in 1938 Congress passed a new Food, Drug, and Cosmetics Act which extended the range of Federal control over drugs and stiffened the penalties, but it is generally recognized that the consumer is not yet adequately statutorily protected by the provisions of the 1938 act as against the dangers to the public health from the use of untested chemical additives on foods. It is for the purpose of adding my support to those who are genuinely interested in protecting the public health against these dangers that I am making this statement before this committee.

What is the present situation with respect to the use of chemical food additives? It is estimated by officials of the Department of Health, Education, and Welfare that of approximately 500 to 700 chemical additives now being used, about 150 have not been adequately pretested to show that they are harmless.

The burden should not be thrown upon the Food and Drug Administration, as it now is under the 1938 act, to discover and prove by a preponderance of evidence that a chemical food additive is poisonous or deleterious to the public health before a product containing such an additive can be banned from the market place. Rather, the burden of proof as to the safety of such a food additive should rest in the first instance upon the manufacturer or processor of such product before it should be permitted to be sold to the consumer.

As the law now stands, the Food and Drug Administration must first prove in court, through libel, seizure, and condemnation proceedings, that a food additive is poisonous or deleterious before it can be proscribed. This means, of course, that during this testing and prosecution period, a harmful or poisonous food additive can enjoy free circulation through digestive channels of the unprotected consumer. The 1938 Food Act is powerless to deal with this problem, since it only applies after the poisoned food has entered the interstate market place and after the injury has occurred. Consequently, the 1938 Food Act needs amendment to correct this situation by providing that the manufacturer or processor of food which contains a chemical food additive must prove to the satisfaction of the Food and Drug Administration that the particular additive is harmless to the public health before the particular article of food can enter the market place. That is the only sensible and sure way in which the public interest can be protected. In case of doubt, the product then should and can be barred from human consumption. And it follows that to perform its proper function under such legislation the Food and Drug Administration should be adequately staffed and financed.

I understand that a number of bills are before this subcommittee proposing various amendments to the 1938 act. I have not undertaken to study them in detail, nor will I undertake to make a comparative analysis of their provisions. However, it is my firm conviction that no bill is entitled to the support of this committee which does not contain the pretesting procedure to which I have referred. And this procedure should apply to all chemical food additives, whether they are now or whether they have been in use for months or years.

No "grandfather" clauses should be permitted. A striking example of this was the use of nitrogen trichloride as a chemical bleaching agent on flour. The trade name of this chemical was Agene. After 25 years' use of it a British scientist discovered that when this bleached flour was fed to dogs it gave them "running fits." Long usage is no assurance of safety. Commissioner Larrick, of the Food and Drug Administration, recently stated that it would take 25 years to recheck colors alone, and that the shortest cancer-producing test on animals takes 7 years. It is unethical and unreasonable to compel the unprotected consumer to undergo the hazards of consumption of questionable cancer-producing food additives while this testing is in progress. Rather, such suspect chemical food additives should be barred absolutely from the market place until the processor or manufacturer can prove to the satisfaction of the Food and Drug Administration that such additives are safe for human consumption. The statutory test should be: What is best for the consumer—not the producer or processor.

Furthermore, the legislation should not be hamstrung by complicated legal enforcement procedures which would defeat the very purpose of the strengthening amendments. On the other hand, in all fairness to the producer or processor whose additive is banned from the market, he should be permitted the full right of judicial review of any adverse ruling of the Food and Drug Administration, such as is now provided by the Administrative Procedure Act in the case of similar administrative determinations.

The purpose of this strengthening legislation as to food additives is to promote consumer welfare by protecting the lives and health of people who cannot protect themselves. Not only must additives be safe, but also they must be shown to have a genuine beneficial and nutritional value to the consumer.

Mr. WILLIAMS. I believe our next witness is Dr. W. C. Martin. Is he here?

Dr. MARTIN. Yes, Mr. Chairman.

STATEMENT OF DR. W. CODA MARTIN, PRESIDENT, AMERICAN ACADEMY OF NUTRITION, NEW YORK, N. Y.

Mr. WILLIAMS. Dr. Martin is president of the American Academy of Nutrition.

Do you have a prepared statement, Dr. Martin?

Mr. MARTIN. Yes, I do.

Mr. WILLIAMS. Has it been submitted?

Dr. Martin, for the sake of the record, would you identify yourself with respect to your education, experience, and background, of course with particular indication as to your qualifications in the field of chemical additives?

Dr. MARTIN. Yes, sir.

Mr. WILLIAMS. Also, if you would, we would like to have for the record the identity of the organization on behalf of which you appear, the way in which it is financed, the number of members, whether the members are individuals or organizations, whether they are scientists or business organizations.

For the sake of the record, could you furnish us that information, in the beginning?

Dr. MARTIN. Yes, sir.

I am Dr. W. C. Martin, of New York City, and I wish to emphasize the fact that I am not a research man. I consider myself a clinician, in that I am a practicing physician, and I am the chief of the geriatrics clinic at the Metropolitan Hospital in New York City.

Also, I am on the staff of the Bird S. Coler Memorial Hospital in New York City, which is the hospital for chronic diseases in older people.

I was graduated from Tulane University in 1928, and for the past 5 or 6 years I have been interested in the problem of geriatrics and the related conditions associated with this, the degenerative diseases.

I have written rather extensively on some of the problems of chemical additives, especially the insecticides, which of course is not on the subject today, but a related subject.

The American Academy of Nutrition is a group of physicians, dentists, and related scientists, with a doctorate degree.

This group is interested in the problem of nutrition in relation to chronic degenerative diseases or in relation to nutrition and health as a whole.

It consists, of course, of some research men, some clinicians, and is, well, you might say, a mixed group of physicians, but many of them are very well known for their research work, and others as practicing physicians.

Mr. WILLIAMS. You may proceed.

Dr. MARTIN. You would like for me to read my statement at the present time?

Mr. WILLIAMS. Yes.

Dr. MARTIN. I take the stand that it is agreed that chemical additives in food have some hazards, and that there is a need for a bill to be passed to protect the consuming public.

The question, in my opinion, and I think it is the opinion of the committee already, as I understand it, is which bill up for consideration is the best bill for the protection, to protect the consuming public, and that is the standard I wish to take.

As president of the American Academy of Nutrition, I have the privilege of representing them at this hearing. At our annual meetin May 1957 a declaration of principles was prepared which stated that the academy approves of the concept of total nutrition from the soil to the human body.

This means quality food, grown on fertile soil and free of chemical additives and chemical residue. It is for this reason that the members share my anxiety as to the health hazards of the chemical additives in food today.

The academy membership, as I have stated, is limited to physicians, dentists, and others with a doctorate in the related sciences.

For several years, as a practicing physician, I have been interested in geriatrics and degenerative diseases. I have particularly been concerned with the harmful effects of some of the chemical additives in foods today.

It has been well established by competent authorities that many of these chemicals interfere with the body's normal enzyme reactions and they are, therefore, directly responsible, in part, for the marked increase in degenerative diseases in the United States today.

Mr. WILLIAMS. Dr. Martin, may I interrupt you at this point, and I beg your pardon for doing so.

Dr. MARTIN. Yes.

Mr. WILLIAMS. I am scheduled to appear before the Rules Committee at 10:30, and I regret very much I will not be able to hear all of your testimony. However, Mr. Dies and Dr. Neal are here, and I necessarily have to leave the committee in charge of Mr. Dies.

Dr. MARTIN. All right, sir.

Mr. DIES (presiding). You may proceed, Doctor.

Dr. MARTIN. This increase in chronic diseases has already become a major medical and economic problem. The continued use of these chemical additives, some of which are known as carcinogens and others or nonnutritive value, can only tend to increase the number of degenerative diseases, including cancer.

A recent survey of chronic diseases in the United States, from such sources as the American Cancer Society, American Heart Association, Foundation for Infantile Paralysis and other authorized agencies, established the existence in the United States of a total of 88,575,000 registered cases of chronic diseases.

Though it is possible a certain percentage of these diseases may be duplicated in one person, it is nonetheless horrifying to project such a figure on the national population of 168 million people.

This health problem is not confined to the older age group. In 1953, Draft Director Lewis B. Hershey stated that the Nation may be "out of manpower" in the next 2 to 3 years, if the present physical standards are not lowered.

At that time, 1,700,000 men out of 4 million examined were rejected as unfit for service. Since then, rejections have reached to approximately 52 percent. This was during the Korean conflict. I have not been able to obtain any figures on the recent draft rejections.

Copies of my report on the Health of the Nation I have given to you as evidence of the number of degenerative diseases that are present.

(The document referred to is as follows:)

HEALTH OF THE NATION

Until recently very little attention has been given to the problem of chronic degenerative diseases. Therefore, very few records are available on mortality and even less on morbidity statistics for these diseases. The classification of specific diseases in this category is still unsettled. This is shown by the fact that only recently the American Medical Association appointed a committee on aging to study chronic diseases and their classification.

In answer to an inquiry, the chairman of the committee stated that so far as they have been able to determine, there are no standard or accepted definitions of the following terms: "degenerative diseases," "chronic diseases," and "chronic degenerative diseases" due to metabolic disturbances.

A report to the President by the President's Commission on the Health Needs of the Nation (1952, vol. 3, table 36, p. 30) includes a list of chronic noninfectious diseases that has been used in meeting request for total mortality from chronic diseases. However, it is not suitable for morbidity statistics. The list is based on the fifth revision of the international list and includes the following diseases:

(1) Cancer and other malignant tumors.
(2) Diabetes mellitus.
(3) Diseases of the heart.
(4) Introcranial lesions of vascular origin.
(5) Chronic and unspecified nehpritis.
(6) Cirrhosis of the liver.
(7) Ulcers of the stomach and duodenum.

Later the sixth revision of the international statistical classification of diseases, injuries, and causes of death divided the mortality statistics into three categories:

(1) Acute diseases.
(2) External causes of death.
(3) Chronic diseases.

The following 25 diseases classified under the sixth revision as chronic diseases are used as the basis for this report.

It has been accepted for the purpose of standardization that a disease that lasts for 3 months or longer is classified as a chronic disease. The majority of these diseases are noninfectious in origin and are known today as chronic degenerative diseases due to metabolic disturbances.

In order to more accurately determine the present health status of the Nation, the United States Public Health Service, in cooperation with the Census Bureau started on January 28, 1957, a nationwide house-to-house health survey. Statistics will be gathered on the number, age, sex, and occupation of persons suffering from diseases, injuries, and handicapped conditions. This survey will give, for the first time, an approximate estimate of the number of people in the United States suffering from illness and physical handicaps. Regular mortality statistics do not give a clue to the number of people that are living and suffering from a chronic condition.

As chronic degenerative diseases are more often found in the older person, it is important to know the population trend of the country. This is shown by the fact that it is estimated that 1 out of 7 older people will be chronically ill each year, that is, for 3 months or more.

Based on this fact we can expect an increase in chronic diseases in the future—as our population is rapidly aging. Although the total population has only doubled since 1900 the number of people age 45 and over has quadrupled. Today, there are over 14 million men and women over the age of 65 years. In 10 years it is estimated that there will be 20 million in the United States 65 years or older. (Report of the Council of State Governments.) It has also been estimated that about half of the people 65 years or older have some form of chronic ailment or physical disability. Another way of stressing the health problem of older people is the fact that although the 65-year or older constitute only 8.2 percent of the population about 40 percent of those stricken for 3 months or longer are in this age group.

There is also an increase in the total population of the country. The United States Public Health Service reports that there will be 4,220,000 babies born in 1957 with a population increase of 2,800,000 people.

In contrast to the marked increase of illness due to chronic diseases, the Health Information Foundation states that there has been a 90-percent drop in the death rate from communicable diseases since 1900. In 1900, pneumonia, influenza, tuberculosis, diarrhea, and enteritis caused one-third of all deaths. By 1956, they caused less than one-twentieth.

Another statistical report which points up the changing pattern of health in the United States, is the fact that the number of general hospital beds in the United States increased 200 percent from 1909 to 1955, although during this same period of time, the population increased only 80 percent.

The increase in chronic diseases is also becoming a major economic problem due to the fact that these people require longer periods of hospitalization, as well as unlimited periods of rehabilitatiton and therapy. Dr. Thomas H. Alphin, director of the American Medical Association's Washington office, stated that the cost of medical care in the United States has been estimated at $11,200 million for private care and $3,900 million for public care, or a total of $15 billion.

In a discussion of the health of the Nation, we often hear the statement that we are living longer than ever before. It is true that the life expectancy from birth has increased from 47 years in 1900 to 65 years for males and 72 years for women in 1957, but the expectancy of life for a man aged 63 years today has increased less than a year in the same period of time. The failure to check the increase of chronic degenerative diseases may even lower the life expectancy of the middle and older age group within the next few years. It is not enough to add years to life, we must add life to the years.

In order to awaken the public's interest in the health of the Nation, it is natural that we must seek the answer to the question of how many people are suffering from a chronic disease which incapacitates them for 3 or more months.

In our search on this problem there is one outstanding fact that is very apparent. There are few or no accurate statistics available on chronic diseases. Vital statistics for mortality do not give an accurate picture of the health of the Nation, because chronic diseases, although debilitating, are usually not immediately fatal. As there is no public danger involved in chronic diseases, compulsory reporting is not demanded. Therefore, it is difficult, and in some cases almost impossible, to obtain accurate statistical data on specific diseases. It is for this reason that we must resort to the best estimates available for the prevalence of the individual chronic diseases. Unfortunately, such estimates are usually only vague approximations to the facts and are frequently used to awaken the public during the heat of a fund-raising campaign by various foundations collecting money for medical research and care of the patients.

In order to find out what the estimates of morbidity for certain chronic diseases are based on, the national health organizations for each of the specific diseases was contacted for available figures. It is interesting to note that in almost every case the organization was aware of the unreliability of the estimates given. The reason for the difficulties of arriving at more reliable estimates of the incidence and prevalence of chronic diseases in the country as a whole, may be summarized as follows:

(1) Lack of medical knowledge in the case of many chronic diseases and consequent lack of uniformity in diagnostic criteria.

(2) Inadequacy of incidence of prevalence surveys: If a representative random sample is selected, while the incidence found may be fairly accurate for the area surveyed, it is hazardous to apply such figures to the country as a whole.

In spite of these handicaps, the available figures for the incidence of chronic diseases in the United States give us sufficient evidence to evaluate the general health status of the Nation.

Upon this basis I present the following figures of the prevalence of individual chronic diseases in the United States today and wherever possible to project the future trend of the disease.

Diseases classified as chronic in the sixth revision of the international statistical classification of diseases are reported and in order of their prevalence:

(1) Allergic disorders, 20 million: This figure includes all types of allergic disorders. Trend: It is known that infatnile eczemas, as well as other allergic diseases, occur more frequently in bottle-fed babies. It is also known that 7 out of 10 mothers use artificial feedings for their babies. Therefore, we can assume that the trend is for an increased number of allergic disorders in the future.

(2) All other diseases of the nervous system and sense organs: (*a*) deafness, 15 million: 15 to 50 million Americans suffer from various degrees of deafness. The small figure is used for our estimate because of the possible inaccuracy of the larger figure. Many cases of deafness are caused by injuries, but the major cause of conduction deafness is otosclerosis, a chronic middle ear bone disease which runs into millions. Trend: With increase in older population, there will be an increase in the incidence of deafness.

(*b*) Blindness, 331,000 (estimate of July 1956): Trend: Approximately two-thirds of all blindness occurs in the later years of life and is caused by cataracts, glaucoma, and other chronic diseases. With increase of the population over 65 years of age, the prevalence rate of blindness may be expected to be on the increase.

(3) Glaucoma, 1 million (Dr. George James, deputy commissioner of health, New York City): Trend: No estimates.

(4) Psychosis and psychoneurosis, 16 million: One in every ten persons of an urban population suffers from one or more well-defined mental disorders. Trend: Rate of mental hospital population in 1903 was 186 per 1,000 population and 328 per 1,000 in 1946. Also, since 1946, one-fifth of the population admitted to mental hospitals was 65 years or more and one-third, 55 years and over. This indicates that the increase of older people will tend to increase the mental health problem.

(5) Mental deficiency, 3 million (mentally retarded children): Actually the estimate is from 3 to 5 million mentally retarded cases today. The conservative figures have been used.

Trend: A recent report from the foundation for retarded children states that there is a mentally retarded child born every 15 minutes in the United States today or about 1,460 each year.

(6) Arteriosclerosis and degenerative heart disease (coronary artery disease), 10 million (estimated based on health survey 1937): Trend: In May 1955, Dr. Paul White and Dr. Norman Jolliffe reported to Congress that the United States is one of the most unhealthy countries in the world in regard to coronary heart disease. The incidence of heart disease among men from 45 to 65 years is 2 to 3 times higher in the United States than in England, France, Germany, Italy, and Spain.

In a paper in the New York State Medical Journal, September 15, 1955, Dr. Jolliffe continued this report by stating, "although in America today, life expectancy at birth is near the best of any civilized country in the world, but at the age of 40, life expectancy is near the bottom."

(7) Arthritis and spondylitis estimate based on collagen diseases, 10 million: Trend: No estimate.

(8) Epilepsy, 1,500,000: Trend: It is believed that epilepsy is more prevalent today than ever before, but the future trend cannot be estimated.

(9) Diabetes (known diabetes), 1 million: A recent survey by diabetic detection centers showed that 2 percent of the population or 3.3 million to be diabetic (Dr. George James, deputy commissioner of health New York City).

Trend: The most recent survey estimates that there are 65,000 new cases of diabetes every year and it is estimated that there are 4,750,000 potential diabetics in the United States. Previous estimate used until 1 year ago was 60,000 new cases each year and 3 million potential diabetics. The committee believes that the increase in the aging population will contribute to an increase in diabetes.

(10) Vascular lesions affecting central nervous system, 1 million (hemiplegia): This figure is based on the estimated number of hemiplegic cases in the United States today.

Trend: This is a disease of the older person, therefore, the increase in the aging population will tend to increase the incidence of vascular lesions affecting the central nervous system.

(11) Malignancy, 700,000: Trend: The United States national cancer institute states that cancer risk is great and that the rate is growing. They also report that one-third of all Americans now living (1 out of 3 people) will probably develop cancer before they die. In 1940 the estimate was only one-fourth or 1 out of 4 people were expected to develop cancer. A more recent report from a cancer detection clinic reported that 228 of 500 women examined (approximately 50 percent) had evidence of a precancerous condition. Three women were found to have an undetected cancer of the cervix.

Another important point to note in the trend of cancer is the occurrence of cancer in the younger age group. In 1923, cancer in children was reported as a medical rarity—today, cancer in children and babies, at birth, is a frequent occurrence. Recently, Boston opened the first hospital in the United States, exclusively for the treatment of children with cancer. It is estimated that there are 500,000 new cases each year.

(12) Tuberculosis, 400,000: Trend: New cases reported exceed 100,000 annually. The treatment of the acute case has improved with the new drug therapy, but this does not change the trend of new cases. No definite estimate for the future trend.

(13) Multiple sclerosis, 250,000: Trend: With the present state of medical knowledge it is even difficult to estimate with any degree of accuracy the number of cases of multiple sclerosis present—for this reason no estimate can be made for the trend of this condition.

(14) All other congenital deformities (cerebral palsy), 150,000: Figures on other congenital deformities are not available at this time. Trend: It is estimated that there are 12,000 new cases each year. No further trend can be determined with the present available information.

(15) Acute poliomyelitis (late stage), 68,000 (infantile paralysis): Trend: With the advent of Salk vaccine, no estimate can be made at this time regarding future cases.

(16) Chronic nephritis: Figures not available at this time.

(17) Chronic rheumatic heart disease: figures not available at this time.

(18) Pellagra: Figures not available at this time.

(19) Hypertension with heart disease: Figures not available at this time.

(20) Ulcers of stomach and duodenum (peptic ulcers), 8,460,000: This number of Americans will be under treatment for peptic ulcer this year. In addition, autopsies indicate that from 10 to 12 percent of the entire population had ulcers at some period during their lifetime (10 percent equals 16,800,000) (Agriculture and Food Chemistry, June 23, 1954). Trend: No estimate.

(21) Cirrhosis of liver: Figures not available at this time.

(22) Cholelithiasis and cholecystitis: Figures not available at this time.

(23) Hypertrophy of prostate: Figures not available at this time.

(24) Ankylosis: Figures not available at this time.

(25) Congenital malformation of circulatory system: Figures not available at this time.

The following are chronic diseases not classified as such in the sixth revision of the international statistical classification of disease:

(26) Nephrosis, 534: The term "nephrosis" was standardized only in the past year. There has been no increase in prevalence.

(27) Alcoholism (chronic), 4 million: Chronic alcoholism ranks fourth among American public health problems. Trend: No estimates available.

(28) Obesity, 32 million: Overweight should be classified as a chronic disease as these people have a mortality rate 1½ times that of people of standard weight according to the Metropolitan Life Insurance Co. It is encouraging to note that weight reduction improves the health outlook of the overweight person. Trend: No estimate.

(29) Muscular dystrophy, 100,000: Conservative estimate ranges from 100,000 to 200,000 cases. Trend: An estimated 20,000 to 30,000 new cases each year.

(30) Parkinson's disease: No figures available at this time.

The grand total of registered chronic diseases in the United States today is 124,959,534.

Subtract obesity and alcoholism; this still leaves 88,959,534 chronically ill out of a population of 168 million people. This is an incomplete estimate as the prevalence of several chronic diseases is not yet available.

In this preliminary report the figures for chronic diseases are given as they were compiled for each disease and without critical analysis for duplication of one or more chronic diseases in the same person. Thus, the total number of people involved may be less than the number reported, but in spite of the possible discrepancies this report reveals a deplorable state of health for the Nation.

This physical degeneration of our bodies has been confirmed by various health surveys on groups of apparently healthy people. A checkup of 500 business executives, average age of 48 years, at the University Hospital, Ann Arbor, Mich., revealed that 41 percent of them suffered from physical diseases of which they were not aware and 77 percent of these healthy men had some form of physical abnormality. Thus, only 23 percent were in good physical health.

In another study, at the University of Pennsylvania, they found that, out of 1,000 apparently well people examined, only 13 percent were entirely free of physical defects.

There are many approaches to the prevention and treatment of such complex diseases but there appears to be one common denominator as the basic cause of degenerative diseases. That one factor is malnutrition. This means overnutrition, as well as undernutrition. When either is present, the body does not receive an adequate balance of nutritional factors to maintain normal cell metabolism; consequently, catabolism or the breaking down process becomes predominant and deterioration of the tissue is the end result.

By way of contrast with this deplorable picture of a rapidly degenerating population is a report made by Dr. Robert McCarrison in the early twenties on the Hunza people of northern India. Dr. McCarrison called them "a group of people unsurpassed in health and physical endurance." To confirm his observation, he ran a feeding test on rats, giving them the same type of food eaten by the Hunza people. These rats lived and reproduced healthy litters for generations, without evidence of disease. Autopsies on the animals revealed no pathology of the organs. A control group of rats fed on diets similar to those eaten by the average American or Englishman developed pathology in nearly all the body organs, similar to the degenerative disease suffered by so many people in the United States today.

I believe that this report on the health of the Nation points out that the urgency of putting into immediate action the 3-year expansion program of the American Academy of Nutrition, the public education program on nutrition, the medical research on the relation of soil fertility and nutrition to degenerative diseases, is a must if this country is to survive as a strong and dynamic nation.

Presented at the annual convention of the American Academy of Nutrition, Los Angeles, Calif., May 25–26, 1957.

Registered chronic diseases in the United States

(1) Allergic diseases	20,000,000
(2) All other diseases of the nervous system	15,000,000
(3) Glaucoma	1,000,000
(4) Psychosis and psychoneurosis	16,000,000
(5) Mental deficiency	3,000,000
(6) Arteriosclerosis and degenerative heart diseases	10,000,000
(7) Arthritis and spondylitis	10,000,000
(8) Epilepsy	1,500,000
(9) Diabetes	1,000,000
(10) Vascular lesions affecting central nervous system	1,000,000
(11) Malignancy	700,000
(12) Tuberculosis	400,000
(13) Multiple sclerosis	250,000
(14) All other congenital deformities	150,000
(15) Acute poliomyelitis (late stage)	68,000
(16) Ulcers of stomach and duodenum	8,460,000
(17) Nephrosis	534
(18) Muscular dystrophy	100,000
Total	88,959,534
Plus Alcoholism	4,000,000
Obesity	32,000,000
Total	124,959,534

Dr. MARTIN. I, therefore, believe it highly important for the health of the Nation that Congress has recognized the necessity for remedial legislation on this problem.

I personally favor the legislation as outlined by Mr. Delaney in bill H. R. 7798, as I believe it gives the public greater protection from the hazards of chemical additives in foods, than the other bills which are being considered.

I particularly approve of the following vital points in H. R. 7798 that are not so well defined in the other bills:

1. Page 1, item 8 (B):

> To preserve or alter any food or any characteristic of any food, including any radioactive material intended for such use.

This point is important for the future protection of foods as more radioactive materials are used in the processing and preservation of food.

2. Page 3, item 12:

> There shall be submitted to the Secretary with the application (1) a statement of the intended use of the chemical additive and demonstrating that such employment of the chemical additive will serve a purpose which will be useful to the consuming public.

The addition of nonnutritive chemicals such as emulsifiers for fats, not only serves no useful purpose to the consuming public, but it also may be toxic.

I think this is a very important point, because if you supplement food by chemicals, the consuming public or the person who buys the food goes with the idea of buying food and not chemicals, and chemicals will not do the work that food will do.

3. Page 5, item 12:

> The Secretary shall not approve for use in food, any chemical additive found to induce cancer in man, or, after testing, found to induce cancer in animals.

As stated, this is an extra safety factor for the protection of the public against carcinogens.

It is my opinion that these and other specific clauses are essential to give adequate protection to the consuming public.

I also believe that the absorption of these toxic chemicals—and there are 704 different chemical compounds used in foods, and 150 of them have never been adequately checked for their toxic effects on humans—over a long period of time can cause serious tissue damage, which inevitably terminates in a degenerative disease.

Many of these chemicals, although apparently nontoxic, have no nutritional value and do not serve a useful purpose for the consuming public. Their continued use, therefore, constitutes a "calculated risk" to human health, if not life itself.

The first line of defense must be to protect the health of the consumer; otherwise, the long-range "calculated risk" is that this country will become a nation of invalids, weak in body and mind.

If you have just a couple of minutes longer, I would like to add a supplement to this. This is more of a clinical approach to the problem or a philosophical approach.

The human body can utilize only natural foods as nourishment and survive. Chemicals are not food elements. Therefore, they can produce only negative or harmful results, even though they are by scientific analysis nontoxic. It is then only a question of how much harm they will produce, when used to replace essential food elements in our diets.

Second, certain chemicals, like stilbestrol, are fed to cattle and other animals for human consumption; yet at the same time the farmer is warned against the use of stilbestrol-supplemented feeds for his stock cattle as the hormone may interfere with their breeding.

This same farmer will give stilbestrol-contaminated meat to his wife who will bear his own child. He also uses the same care in the choice of whole natural foods for his cattle. Yet he accepts chemical substitutes and refined and adulterated foods for his children.

This is a philosophical paradox worthy of psychological research.

Third, the controversy over the hazards of chemicals in cigarettes must be placed in a separate category from chemical additives in foods. In this case, an adult, of his own free will, may choose to gamble with his life and health.

When chemicals are added to foods, there is no choice. People of all ages must eat these foods in order to survive, even though it may be a shorter time than his normal life expectancy.

Most people are unaware that they are consuming adulterated foods. But there are some people who are aware of the hazards of these chemical substitutes, and carefully select their food for nutritional quality, without refinement or adulteration.

In case of the farmer selecting such food for his cattle, he is said to be an intelligent man. In the case of people making the same selection of foods for themselves, they are often called food faddist. This is another philosophical paradox.

Fourth, may I suggest when chemicals are used in foods, they should be labeled "economic supplements," a term similar to "economic poisons" used for insecticides. We then would not be fooling ourselves. I can assure you that we are not fooling the cells of our bodies with these chemicals.

Health of the people and defense of the country are two factors that are more important than simple economy. Food should be standardized for its nutritional value only.

These are some of the philosophical factors that should be considered along with the purely chemical factors before deciding which one of these food additive bills gives the consumer the greatest health protection and becomes the law of the land.

I thank you very much.

Mr. DIES. Thank you, Doctor.

Mr. Loser, do you have any questions?

Mr. LOSER. Nothing at all, thank you, Mr. Chairman.

Mr. DIES. Dr. Neal, do you have any questions?

Mr. NEAL. Doctor, I am sorry I did not get to hear the first part of your statement.

Dr. MARTIN. Yes, sir.

Mr. NEAL. I just wonder, as a physician interested in chemical additives and that sort of thing, do you happen to know at this particular time whether there are any chemical additives to bread or candy or to anything for human consumption, that are actually dangerous to the human body?

Dr. MARTIN. I can only take the word of the research authorities like Dr. Hueper, of the United States Public Health Service, that says these are dangerous.

Mr. NEAL. How many of those things do you refer to, just what specific drugs or chemicals?

Dr. MARTIN. Well, any chemical that supplements a nutritive element in food, like some of the emulsifiers that are used in place of cream and fats and butters, that is a chemical supplement.

In other words, that will not give the body the same food value that the butter and fats will give, and, therefore, as I say, this is considered a nontoxic substance, but you are depleting the body of some of the elements it should be getting.

Mr. NEAL. You are speaking of chemicals in general without particular reference to any specific one.

We know that probably there is some experiment and possibly some chance being taken by food processors in using chemicals. We know, too, that the human body has a wonderful way of either excluding and throwing off anything that is taken into the human system that it did not particularly use.

We know full well that excesses of vitamins produce no particular harm; those that are not especially needed are simply thrown off in waste by the body.

We fully realize that there are a good many chemical components of the human body. Do we not have to assume that it is necessary that they be greatly in excess of natural chemicals that go into the makeup of human foods in order to be deleterious to the human body?

Dr. MARTIN. Some of your statements I cannot exactly agree on, because it is very well known, and with much clinical evidence and research evidence to back it up, that some of the excess vitamins do cause harm. Excess vitamin A, hypervitaminosis, is a very dangerous thing.

Of course, it is not likely to occur, but it does occur in quite a few cases, and many have been reported recently.

As far as the other thing, you say the body can throw off these things, but as the body throws them off, they are doing minute damage to the liver, which is the detoxifying agent, and that will go on for a certain length of time, and sooner or later the damage is produced, and that is where our chronic degenerative diseases come in.

Sometimes it takes even 2 or 3 generations to produce this damage, but inevitably it will be produced. And if we are interested in the long-range health of this Nation, then these factors have to be taken into consideration on a long-range program, not the immediate 6 months or even 1 lifetime, and these experiments have been done, also.

Mr. NEAL. You made the statement here that approximately 704 different chemical compounds are used in foods.

Dr. MARTIN. Yes, sir.

Mr. NEAL. And, so far as you know, in your statement, that 150 of them have never been adequately checked.

Dr. MARTIN. That is the statement of the United States Public Health Service. I am taking their word for it.

Mr. NEAL. I think that is probably true, from other evidence which has been given here.

Dr. MARTIN. Yes.

Mr. NEAL. Would you have any idea just what the expense would be or the details of trying to figure out what would be the harmful effects of any specific additive to food?

Dr. MARTIN. I think it would be very terrific, and the point I tried to bring out here, and I think I brought out originally, is that the thing we are discussing today is not leaving out all of these chemical additives, because apparently under our situation, environmental and economic, and the type of civilization that we live in, it is probably not possible.

We have several bills for consideration here. I particularly favor Mr. Delaney's bill because I think it gives better protection to the public, and certainly his bill does not say you are going to eliminate all of these things.

My point is that the lesser or the fewer of these chemicals we get in our food, the better our health will be. And that is the point: keep them down to a minimum.

Mr. NEAL. Well, that would be insofar as additives from the standpoint of nutritional value are concerned.

Dr. MARTIN. That is what I am interested in.

Mr. NEAL. So far as additives that preserve foods for human use, would you not think that the average consumer of food that is possibly contaminated because of the lack of preservatives will be more dangerous than the longtime ill effects which might come from the addition of these chemicals?

Dr. MARTIN. Certainly those factors have to be taken into consideration. But when you are using some preservatives, as apparently we are today, that are really toxic in nature, and some of them in the field of carcinogens, then that is a different problem altogether. Certainly those should be eliminated completely from the foods.

Mr. NEAL. Do you know now of any specific element which is being added to foods which is actually to be considered as a carcinogen?

Dr. MARTIN. Right here, Dr. Hueper in his statement at the Rome Conference last year outlines, says, another list containing 23 dyes that

might prove satisfactory for further tests—somewhere he names 20 different chemicals that are possibly carcinogenic. I have the list here of them, that are being used today.

Mr. NEAL. That are being used now?

Dr. MARTIN. Yes. I am not a research man. I had to take his word. He is one of our outstanding chemists in the United States Department of Health, the United States Public Health Service, and I am taking his word. He has done this research and shown these to be possible carcinogens.

Mr. NEAL. I think the move to regulate and to require pretesting of additives prior to the time they are introduced into food products, is a good one. There is no question about that.

Dr. MARTIN. That is right.

Mr. NEAL. The big question with us on the committee, as I have been able to observe here, is attempting to arrange such a plan for the control of those things as will not too heavily bear on the duties either of the courts or the expenses of the food processors in actually trying to solve the problem and to handle this thing legitimately.

Dr. MARTIN. I agree with you on that.

Mr. NEAL. The question of carcinogens, I think, is still very much unproved except——

Dr. MARTIN. That is a hard thing to prove, as you know, about the cigarette controversy at the present time. The two sides have not even agreed on that, and I think we have probably more research done on that than any other one thing, and if they cannot agree on that, certainly they are not going to agree on a few of these things.

Mr. NEAL. The advertisements pro and con, we see there are always two sides to every question, and particularly——

Dr. MARTIN. Yes. But my point was that in foods which are consumed by everyone—men, women, and children—for the rest of their lives and for generations to come, we have to be more careful than we would, say, in cigarettes and things that a person has a choice of whether he likes them or not.

Mr. NEAL. Do you think the requirement, as testified to here, as presented here in Mr. Delaney's bill, that henceforth—admitting maybe food additives that are being used now by commercial food processors are safe, that henceforth the requirement that all new additives intended to be used in food shall be pretested, will practically solve the problem so far as the general health of the public is concerned?

Dr. MARTIN. Well, there are these 150 that have never been tested. Are they going to be left in the foods?

Mr. NEAL. Well, I think, according to the proponents of the terms of this bill, you require that before any additive may be used by the processor——

Dr. MARTIN. That means any we have used in the past or future?

Mr. NEAL (continuing). He will supply the information that it has been tested and is perfectly free of injurious effects.

Dr. MARTIN. Yes, I think that is a very important point.

Mr. NEAL. If we take that particular legislation and carry it out properly, do you think that insofar as our interest in the health of present and future generations is concerned, we are on the right track?

Dr. MARTIN. That is a step toward the right way. As I say, I do

not think we can eliminate everything today, although we always look for and have a mind toward the ideal goal. We do not always reach it, but that is a step forward, and I think that is the point of all of these bills, which is to improve the situation.

And it is just my opinion; I felt that some of the facts in Mr. Delaney's bill gave a little more protection than the others.

Mr. NEAL. I notice you mentioned the effect of stilbestrol and similar products being used in animal foods.

Dr. MARTIN. Yes, sir.

Mr. NEAL. I think your point is well taken there, because unquestionably insofar as their use by humans is concerned, there is a great deal of question yet as to what the ultimate effects, the experience with hormones of that type, will be. They have not been sufficiently studied and observed to make any definite rule of safety or otherwise.

Dr. MARTIN. That is right.

Mr. NEAL. So perhaps control of the use of that sort of thing, even in animal life, is just as important as it is to refrain from general use of that sort of thing, until after we have determined more definitely just what the immediate as well as the long-time—I mean the long-time as well as the immediate effects are.

Dr. MARTIN. That is right.

I understand practically all the cattle coming on the market today are being fed food with stilbestrol in it, so we are getting it today.

And many of the chickens, you notice, the caponettes—they have given them a special name—have stilbestrol in them. So we are getting our dose of stilbestrol today.

Mr. NEAL. Well, we all have difficulty in trying to determine the basis of that drug, inasmuch as we have tradenames for practically everything that comes out of the processors of medicine at this time.

Thank you very much, Doctor.

Dr. MARTIN. Thank you.

Mr. DIES. Thank you, Mr. Martin.

(The article on diethylstilbestrol submitted by Dr. Martin is as follows:)

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POSSIBLE CANCER HAZARD PRESENTED BY FEEDING DIETHYLSTILBESTROL TO CATTLE

Granville F. Knight, M. D.,[1] W. Coda Martin, M. D., [2] Rigoberto Iglesias, M. D.[3] and William E. Smith, M. D.[2]

Introduction of the powerful drug diethystilbestrol into the Nation's food supply prompts consideration of the actions of this compound. It is known to induce cancer.[4 5] It has also been found to stimulate weight gain. For the latter reason, there has developed a practice of administering this drug to poultry and beef cattle in the United States.[6]

It has been estimated that more than 30 million chickens per year are implanted with pellets of diethylstilbestrol and that approximately half of the feedlot cattle

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[4] Hartwell, J. L.: Survey of compounds which have been tested for carcinogenic activity, Washington, D. C., U. S. Public Health Service Publication No. 149, 1951.
[5] Homburger, F., and Fishman, W. H.: The Physiopathology of Cancer, New York, Paul B. Hoeber, 1953.
[6] Fournier, W. C.: New hormone drug fattens cattle quicker, The Wall Street Journal, September 9, 1955, p. 1.

in the country are now given feeds to which this drug has been added. In poultry, the pellets are intended to be inserted at the base of the skull on the supposition that this part will be discarded and not eaten. But among nine lots of poultry coming into the New York market and examined by inspectors of the Food and Drug Administration, about 35 percent of the birds were stated to contain such pellets in the neck. Similar findings emerged from subsequent investigations ,and the residual diethylstilbestrol was reported as 3 to 24 milligrams per bird.[7] It has been claimed that no appreciable quantities of diethystilbestrol can be demonstrated in the tissues of cattle fed this drug,[8] but this claim may convey a false sense of security for reasons subsequently given in this presentation.

Diethylstilbestrol can be made under conditions involving exposure to a temperature of 428° F. for several hours.[8] The temperature recommended for roasting chickens is 350° F. Temperatures of only 140° to 180° F. are found in the interior of roasts of beef.[9] From these figures, it is apparent that diethystilbestrol would not be destroyed by cooking and could be conveyed to consumers of meat containing it.

It thus seems pertinent to review the effects that this compound can exert. Administration of estrogens, among which diethylstilbestrol is one of the most potent, has led to a wide range of pathologic changes in human beings and in animals. In mice, rats, or guinea pigs, estrogens can induce polyps, fibroids, and cancers of the uterus, cancers of the cervix, cancers of the breast, hyperplasia of prostatic stroma and of endometrium, tumors of the testicle and hypophysis, and leukemias.[5]

In the experience of one of us (R. I.), uterine tumors have frequently been found in guinea pigs given as little as 1.5 milligrams of diethylstilbestrol or other estrogens in subcutaneously implanted pellets.[10 11] Indeed, tumors have resulted in guinea pigs exposed to as little as 8 μg. (0.008 mg) of diethlystilbestrol per day.[10] Lower dosage levels have not yet been tested in guinea pigs, but in current experiments a pellet removed from a guinea pig 1 year after implantation has been found to retain sufficient activity to induce a tumor upon reimplantation into another animal.

Investigators at the National Cancer Institute [12] have reported that cancers of the breast can be induced in mice by as little as 0.07 μg. of diethylstilbestrol per day. This dosage sufficed to induce breast cancer in about 50 percent of male mice, who do not develop such tumors in absence of exposure to an estrogen. A total dose of 30 μg. was effective in these experiments in which the drug was administered in a subcutaneously implanted pellet. These and other investigators found that diethylstilbestrol also induced tumors readily when given to mice by mouth. Normal mice excrete between 0.05 and 0.1 μg. of estrogen per day.[13] So delicate is the physiologic balance that exposure to an approximately equal additional amount (0.07 μg.) of estrogen (diethylstilbestrol) per day suffices to induce cancer, as previously mentioned.

From these findings, it is obvious that the cancer-producing dose of this drug approaches the infinitesimal. Claims that no appreciable quantities of it can be demonstrated in tissues of cattle to which it has been fed must therefore be carefully scrutinized as to the sensitivity and accuracy of the test methods, An equally cogent consideration is that the fundamental mechanism of cancer induction by diethylstilbestrol is not understood. Many tumors are known to be caused by viruses.[6] In mice, cancer of the breast has been traced to a virus, but, for its cancer-producing activity, this virus is dependent upon stimulation by estrogens, such as diethylstilbestrol. This virus remains in the tissues and exerts its neoplastic effects long after cessation of administration of estrogens. Absence of detectable estrogen in the tissues of animals treated with or fed such a substance thus offers no assurance of the absence of a cancer hazard in such tissues.

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[7] Wickenden, L.: Our Daily Poison, New York, Devin-Adair, 1955.

[8] Twombly, G. H.: Tissue localization and excretion routes of radioactive diethylstilbestrol. Acta Union International contre Cancer, *8*: 882–888, 1952.

[9] Farmer, F.: The Boston Cooking School Cook Book, Boston, Little, Brown & Co., 1944.

[10] Lipschutz, A.: Steroid Hormones and Tumors, Baltimore, Williams & Wilkins Co., 1950.

[11] Lipschutz, A.; Iglesias, R., and Vargas, L.: Uterine and extra-uterine localizations of experimental fibroids inducted in guinea pigs by prolonged administration of estrogens, Proc. Soc. Exper. Biol. & Med. *45*: 788–792, 1940.

[12] Staff of the National Cancer Institute, U. S. P. H. S.: A symposium on mammary tumors in mice, Washington, D. C., Am. A. Advancement of Science, Publication No. 22, 1945. p. 97.

[13] Aub, J. C.; Karnfosky, D., and Towne, L. E.: Sex hormone excretion rates in high and low tumor strains of mice, Cancer Research *1*: 737, 1941.

A great body of evidence shows that cancer-inciting chemicals can exert their effects in catalytic quantities, inducing changes in cells which are mediated by unknown substances transmitted from cell to cell long after the original cancer-inciting material ceases to be demonstrable in the tissues.[5] No assurance of the absence of such substances can be offered consumers of tissues from animals treated with or fed a carcinogen, such as diethylstilbestrol.

In human beings a variety of pathologic changes have been found to follow administration of estrogens. In women well past the menopause, the course of breast cancer is slowed by estrogens, but in somewhat younger women it is accelerated.[14] There are claims for primary initiation of cancer in women by estrogens,[15] but these have been few in contrast to the great number and diversity of tumors following estrogenic treatment of animals. Now it has been found from animal experiments that the spacing of doses greatly influences the yield of tumors. Most important, it has been learned from animal work that intermittent administration of very large doses of estrogens is far less effective in inducing tumors than is a continuing exposure to an extremely minute dose. This phenomenon has been repeatedly observed by one of us (R. I.) in experiments conducted over a period of nearly 20 years with Lipschutz.[10] It is a continuing exposure to extremely minute doses that is to be feared from the introductions of estrogens into the food supply.

A prime consideration is the long period of time that elapses between first exposure to a carcinogen, such as diethylstilbestrol, and eventual appearance of a tumor. In animal experiments, exposure is customarily begun early in life and the majority of tumors arise when the animals are old. Experience in the results of administration of estrogens to human beings has been largely limited to treatment of conditions arising fairly late in life. By comparison, the majority of human beings thus far exposed would complete their life span before passage of sufficient time to observe a carcinogenic effect of estrogens. The introduction of estrogens into the food supply, however, presents the problem of exposure of human beings from birth onward. That human beings are not immune to the cancer-inciting action of estrogens is shown by the fact that there are on record some 17 cases of cancer of the breast in men given estrogens, including diethylstilbestrol.[16 17 18]

Figures were presented to this symposium[19] which, according to our understanding, represent the finding of about 1 μg. of diethylstilbestrol per pound in the tissue of a steer given the prescribed amount of 10 milligrams of this drug in feed. One pound of such tissue would thus contain about 14 times the amount of diethylstilbestrol needed as a daily dose to produce cancer in mice, for, as previously stated, 0.07 μg. of diethylstilbestrol per day sufficed the elicit cancer in about 50 percent of mice. Furthermore, claims for the absence of diethylstilbestrol in tissues have been based on a method whose limit of sensitivity[6] is, according to our calculations, in the range of 1 μg. per 1.1 pounds. This means that a pound of meat, certified as free of diethylstilbestrol, could contain nearly 14 times the amount of this drug necessary to induce cancer by a daily dose to mice. In the case of market poultry found to contain up to 24 milligrams of diethylstilbestrol per bird,[7] one is dealing with an amount roughly equivalent to 342,000 times the daily dose necessary to produce cancer in mice.

It would therefore seem prudent that further careful consideration be given the matter of adding to the cycle of food supply a drug known to initiate or aggravate a serious disease.

Mr. DIES. The next witness is Mr. George D. Riley, legislative representative of the AFL–CIO.

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[14] Fischer, G. C.: Hormone therapy in advanced mammary carcinoma, M. Clinics North America 36: 681–688, 1952.

[15] Novak E.: Uterine adenocarcinoma in a patient receiving estrogens, Am. J. Obst. and Gynec. 62: 688–690, 1951.

[16] Hueper, W. C.: Recent developments in environmental cancer, A. M. A. Arch. Path. 58: 475–523, 1954.

[17] Graves, G., and Harris, H.: Carcinoma of the male breast with axillary metastasis following stilbestrol therapy. Ann. Surg. 135: 411–414, 1952.

[18] Jakobsen, A.: Bilateral mammary carcinoma in the male following stilbestrol therapy, Acta Path. et Microbiol. Scandinav. 31: 61–65, 1952.

[19] Gossett, F. O: The feeding of high levels of diethylstilbestrol to beef animals. In: Symposium on Medicated Feeds, New York, Medical Encyclopedia, Inc., 1956.

STATEMENT OF GEORGE D. RILEY, LEGISLATIVE REPRESENTATIVE, AFL–CIO

Mr. RILEY. Good morning, Mr. Chairman.

Mr. Chairman, I have a prepared statement which I would like to submit for the record, and make a few informal remarks.

My name is George D. Riley. I am legislative representative for the AFL–CIO.

We support the Delaney-Sullivan bill. We believe this bill most nearly meets the needs of consumers who, in our opinion, are quite important persons.

We do not oppose any bill which the committee may amend to include the principal features designed to conclusively protect consumers from elements which have not been proved non-cancer-promoting or otherwise toxic.

Primarily, the one-hundred-and-fifty-odd additives remaining in the scientific no man's land, in our opinion, should be proved up before they are permitted further use.

If any of these additives shall be adjudged to be useful only to create the illusion of quality, they seem not to have proved their right to enter the human body.

The terms "safe dosage" and "long usage" should not be tolerated as an excuse for weakening the legislation.

As our contribution to the discussion on how appeals by the industry shall be channeled, the Administrative Procedure Act provides a clear beacon. This act is consonant with what prevails for other regulatory agencies.

Mr. LOSER. I did not understand, Mr. Riley; what was it you said?

Mr. RILEY. We feel the Administrative Procedure Act affords adequate and complete relief to the industry if they are not satisfied with the decisions made administratively by the HEW.

Mr. NEAL. You feel that the Administrative Procedure Act affords complete relief for the situation without further reference to it in future legislation?

Mr. RILEY. I cannot quite hear you, Doctor. If you do not mind, will you please repeat it?

Mr. NEAL. I say you feel that the powers under the Administrative Procedure Act as existing at the present time are sufficient, without any additional judicial procedures here in this bill?

Mr. RILEY. I think so, sure.

Mr. NEAL. Yes.

Mr. RILEY. Yes. It affords relief for appellants before other regulatory bodies, and we see no reason to set apart this industry as an exception to the operation of the Administrative Procedure Act.

Mr. NEAL. Yes.

Mr. LOSER. Excuse me for interrupting you.

Mr. RILEY. Yes, sir.

We maintain all doubts in this legislation must be resolved in favor of the consumer.

The Congress in the last 10 days has spoken very affirmatively on a piece of legislation which is in this general field, and that is the Poultry Inspection Act which, by a negative vote of 23, passed the House some 10 days ago.

There was difficulty getting that act finally completed. It is now waiting for the Senate Agriculture Committee to act, and I have full confidence that it will be on the President's desk in the foreseeable future.

It took some 2 years to get that act to the point it is today. There was resistance. There were all kinds of ifs, ands, and buts on what should be done about these communicable diseases which constituted a hazard to those employed in the industry and those who are consumers.

Bear in mind that poultry is the third largest agricultural product, and it is well distributed in practically all of the States, so far as I know, in the union; and, therefore, there was an interest, industrywise, in that legislation.

Last year, there was a considerable, I sensed, resistance to that legislation. This year, everybody got on the bandwagon.

That bill is an excellent bill, and I am convinced from my years of observation on this Hill that once the Congress gets in the direction to act in this type of thing, that it always comes up with a good and proper answer.

Mr. DIES. Thank you, Mr. Riley.

Do you have any questions?

Mr. LOSER. Not at all.

Mr. RILEY. If I may offer what I think is a helpful suggestion to Dr. Neal, the doctor was not in the Congress last year when there were hearings on this subject. I have had occasion recently to review the proceedings from last year, and I noticed that specifically bread softener was mentioned.

I think you expressed an interest a while ago in that subject, and if I recall, the hearings showed that this particular chemical was being produced by the Atlas Powder Co., and there was a considerable discussion before this committee on that subject, none of which I can remember was very friendly to the product involved.

Mr. DIES. Thank you, sir.

Mr. RILEY. Yes, sir.

(Mr. Riley's prepared statement is as follows:)

STATEMENT OF GEORGE D. RILEY, AFL–CIO LEGISLATIVE REPRESENTATIVE

The AFL–CIO endorses the general purposes of the bills under discussion and presents its views in support of legislation to provide food supplies safe from untested chemicals.

I hope your committee will take encouragement from the results of a crusade of less than 2 years in the Congress to stamp out filth and disease communicable to humans from handling and consuming poultry, the third largest agricultural product.

An aroused public quickly came to the realization that their stomachs and general well-being were involved. That campaign probably was the shortest of any the Congress can recall, involving the safety of tens of millions of citizens.

The industry, though slow in coming to life on the poultry inspection legislation, did understand the necessity of choosing sides. It chose to take the right side.

Until now, it appears the food industry in general may take a while longer to take a firm and unequivocal stand in support of consumers. Such standpatism cannot endure.

Some of us know the story of how formaldehyde was applied generously by some meatpackers, during the Spanish-American War, on food intended for our soldiers.

It took 9 years to bring the pure food and drug law to the books in 1906. That same year, the Red Meat Inspection Act became law. Both laws have continued for half a century with clear and conscientious enforcement ever since.

I am sure no one would attempt or wish to see repeal or weakening of either law. The Federal Food, Drug, and Cosmetic Act is an even stronger law than its predecessor.

Yet, the impelling reasons for enacting those laws probably could be said to be not so strong as the reasons for approving one of the present bills before your committee.

This is true because today we are in the age of chemistry as well as the age of the atom.

Chemistry, 50 years ago, had not dared to beat down more than a small fraction of the frontiers it has today. Few companies today, whether in the field of food processing or preservation, are without their chemical laboratories. These are known to the public largely as research centers or departments.

In any event, most chemists on their companies' payrolls of necessity must exercise their diligence in the direction pointed out by the employers.

Their jobs obviously include devising stabilizers, moistening agents coatings, bleaches, emulsifiers, neutralizers, preservatives, antioxidants, modifiers and a long list of other chemical considerations.

The Assistant Secretary of HEW last year pointed up the problem quite well when he told the American Chemical Society that:

"Advances in food chemistry and food technology have brought about a tremendous increase in the use of various kinds of additives, but there is no law which requires that these be tested and found safe to the consumer before they are put on the market. The law is not preventive—it is merely punitive, imposing penalties on the use of those additives which have been proved to be harmful. In very many cases it is difficult, if not impossible, to secure such proof. Additives of questionable safety may continue to be used since evidence is lacking of any harmfulness. The backlog of research needed to establish safety of all these materials has grown to the point where it far exceeds the resources and scientific personnel of any Government agency. In fact, a recent report on the FDA research program on coal-tar colors says that it would take 25 years for the present staff to complete the studies in that one field which should now be undertaken."

Whether the purpose of injecting these agents into food to provide eye appeal or toothsomeness or solubility, none of these in itself carries with it a warranty of wholesomeness or guaranty against cumulative toxicity.

In 17 years, more than 25,000 chemical food additives or substances have been considered for use in food intended for your consumption or mine. Some 20,000 of these 25,000 have been eliminated as acutely toxic.

Another 4,000 have been eliminated as subacute and chronic toxic. Still another 600 have been eliminated for other reasons, leaving 400 others in use for one or the other of these reasons:

1. 150 in use without adequate testing.
2. 100 safe within limits of use.
3. 150 harmless and now are in use.

These means that of the 25,000 food additives, at least 300 substances are suspect. It is difficult to understand how an additive can be "safe within limits of use" and still not be unsafe also within limits. But it is not difficult to understand the potentials of 150 others which are being used every day without adequate testing.

There has been much discussion of the possibility or probability of promotion of cancer. If such suspicion be well-grounded, those 150 untested additives seem to be the villains.

Because these 150 are not adjudged safe and because no agency seems empowered by statute to separate the safe from the unsafe, you have these bills on the table.

We have taken note of the several hearings during 7 or more years in an effort to guarantee consumer health safety. We also note that more than one bill each this year has been introduced by several sponsors.

We are convinced that these several bills represent efforts to phrase the measures in their best and most comprehensive terms. This, we recognize as a serious attempt to enact legislation this year.

Included in this number are Representative James J. Delaney, chairman of the one-time Select Committee on Chemical Food Additives who performed great service in this cause, and Mrs. Leonor Sullivan whose bill is similar to that of Mr. Delaney.

The sponsor of each bill before your committee has earned much credit for presenting a measure on this vital issue.

These bills are reasonable. We can only view opposition to them, direct or indirect, as an unfriendly stand on the good and welfare of consumers in general.

In a highly competitive world where balance sheets, sales volume, annual reports and dividend payments are prestige items with processors and handlers, the first to burst forth with a new slogan, gadget, label, claim with the best pop-crackle jim-crack for the family youngster also gets the jump on the competitors.

This determination to be first to the consumer's purse could be more easily tolerated if we knew for a fact that some additives do not cause bladder cancer, skin cancer, stomach cancer or any other malignancy.

Now is the time to empower the Department of Health, Education, and Welfare to be authorized and directed to get the programs outlined in these bills started.

Most important is to realize that, in the minds of the experts, there is no safe dose of a cancer-producing chemical.

We read the news of findings of authorities who say cancer, under certain conditions of smoking, is possible. We are warned about tars in cigarettes and we are told of the great risk from fallout in atomic bombs.

The "atomic bombs" which go into our stomachs we delay doing something about. These bills are not "class legislation." They affect and include every person, without exception.

A report on this legislation even this year, will be a half century behind the time the original pure food bill was enacted.

I notice some bills defer the effective date 1 year beyond time of enactment. This is too long. Six months would appear to be ample time to accommodate all parties.

SUMMARY

It has been suggested that the cost of administering this act should be charged to the industry. As a matter of fair play, this seems to be subsidizing the Government to do what it ought to do. The poultry inspection legislation will be paid for by the Government, just as other acts of similar type are. The ultimate consumer is going to pay the cost in the long run, no matter who pays it for him in the interim. We suggest the Government defray the cost meanwhile, then the Government, as the "fiddler," can call the tunes.

There probably will be suggestions that another general and thorough investigation of the chemicals-in-food situation be launched, as was done when Mr. Delaney was chairman of the select committee. As a general proposition, investigations have their good effects. At the same time, they further delay enactment of substantive legislation because everything stops until the investigation report is completed.

The need now is for action without further delay. If it is indicated that after this act gets underway investigation to learn how the act is operating, then would seem to be the time for investigation.

There doubtless will be those who will say that the district courts are the proper place for judicial review. Others will say it should be the appeals courts. And others will go for declaratory judgments. Then the grandfather's clause will get some place in the discussions. Whatever in the committee's judgment will promote the beneficial effects of this legislation and with the least delay, that is our preference.

The fact is that today all of us are walking chemical additive containers. Until all such additives have been pretested, we do not know whether those additives will show up years hence to prove our undoing, whether children today will reap the full ill-effects promptly or after arriving at adulthood.

APPENDIX

The following is an excerpt from House Document No. 227 (84th Cong.) titled "Citizens Advisory Committee Report" and dealing with food programs. Mr. Lee W. Minton, president, Glass Bottle Blowers Union (AFL–CIO), was a member of the Citizens Advisory Committee:

CHEMICAL ADDITIVES IN FOODS

FDA responsibility on the subject of chemical additives is described under sections 402 (a) (2) and 406 of the act, wherein it is required to preclude the use of any unnecessary and avoidable poisonous or deleterious substance in food.

Chemical additives involve all of those substances not natural to a food in its basic or purest state which are used by manufacturers to affect the normal characteristics of the food. Several years ago informed sources estimated that such substances in regular usage numbered in the hundreds. These materials are generally, but not always, used for desirable or healthful ends, such as preserving of nutritive values, prevention of spoilage or decay, improvement of appearance, promotion of softness, tenderness or flavor, etc. In other, and rarer instances, the substance may be used solely for the purpose of disguising the inferior quality of the food. There is general use of these materials by the food industry and consumers have frequently, through preference or demand, as in the case of bread softeners, made such use almost mandatory.

To cope with its present statutory duty with respect to such materials, the FDA finds itself faced with the problems of discovering the fact of their use and of determining the necessity and effect of such use.

It is estimated that there are thousands of establishments (100,000 estimated) in the United States in which additives may be used in or on foods which go into interstate commerce. Yet the present FDA staff is able only to inspect slightly more than 10 percent of these in any one year.

Industry has at its disposal, and is using, thousands of scientists who are constantly developing new additives or new means of putting old ones to advantageous use. Many of these substances, and their uses, are highly complex in nature, and frequently secret. Thus, under present law, the FDA has a need for expert technologists, with modern analytical equipment, to create means of identifying additives in foods. Then it must devise and conduct involved tests to ascertain the elements of acute and chronic toxicity. Finally, it must determine whether the use is necessary and unavoidable.

From time to time it has been said that the FDA is overtechnical in its interpretation of the terms "necessary and unavoidable" and thereby precludes the use by industry of substances claimed to be essential to providing the consumer with better foods at lower prices. FDA also has been charged with being too stringent, even unrealistic, in its appraisal of what is "poisonous or deleterious," particularly in the realm of chronic toxicity. While there is some evidence these charges may have been true in a few isolated cases, in the area of prevention of food poisoning FDA stands on firm ground, and the errors made have been in human zealousness for a humane cause. It is to be doubted that they were made, or will be continued as a matter of policy.

In the field of chemical additives FDA has a tremendous responsibility which is becoming increasingly difficult to appraise. Its personnel and facilities have been grossly inadequate in a most hazardous area.

It is understood that an amendment of the act has been proposed which would provide for the pretesting of "new chemicals" in foods by manufacturers of chemical additives. It is expected that this legislation, if adopted, would materially affect the responsibilities of the FDA in this area by simplifying some existing responsibilities and adding others, and would require a complete reappraisal of currently overextended resources.

PRINCIPAL FOOD COMMODITY GROUPS

The principal food commodity groups affected are to be found in appendix E. In general, it is apparent that FDA's activities have been directed to the prevention and correction of bad conditions in only the most critical cases. There has been little time or facilities for anything else.

It is true that FDA has been charged with overzealousness in its enforcement techniques, in emphasizing programs where the health or economic importance was not of primary importance. But frequently such activities have been necessary to nip in its incipiency a course of conduct which would lead to flagrant abuses and substantial injury. Unquestionably, FDA enjoys a reasonable, cooperative reputation with responsible representatives of the industry, and the major sources of complaint against it seem to be from that small group of marginal operators who exist in every enterprise.

In general, FDA's programs are well organized to effect the most reasonable working control with and over all the food producers, in substantial proportion to the frequency of hazards and prospective violations of law involved. Some changes could be made looking toward improved efficiency, but the facilities and time are lacking for a truly adequate planning for these, and even then, with existing fund limits, such may merely result in a shifting of the risk, with little reduction of it.

CURRENT SPECIAL PROJECTS

In addition to its normal activities, FDA currently has a large group of special projects which require attention. These arise out of ususual economic or trade situations and are usually of an urgent nature. All are designed to afford more adequate protection to the consuming public and industry under the law and all would be beneficial. It appears a few of these special projects are of lesser true public importance, but the overwhelming majority involve serious situations, the control of which is imperative.

Complexities arising out of the growth of volume, new products, technological developments in production, and new marketing techniques in such food fields as bakery, cereal and macaroni products, beverages, dairy products, fish, frozen and concentrated fruit juices, poultry, and special dietary food have imposed a greater burden than the FDA with its present limited staff can meet.

The recent grain-sanitation program, handicapped as it was by the huge volume of goods involved, the large percentage of this commodity held in Government storage programs, and the conflict of interest with the Department of Agriculture, presents a very complex problem for the FDA and the Federal Government.

With the pressure of routine activities, FDA has insufficient facilities to do more than scratch the surface of special problems which are arising constantly and, even if they do so, their general program suffers. The great majority of these projects are essential for the protection of the public health and the economic status of the affected industries.

FILTH, INSANITATION, AND DECOMPOSITION

One of the most important phases of FDA's statutory responsibilities is the control or elimination of filth, insanitation, and decomposition. All are real problems in the food field, because insect infestation and rodent contamination are constant threats, the raw materials are subject to rot or deterioration, and because of the size and number of processing and handling establishments.

The courts have long ago decided that proof of the immediate or incipient injury to health is not essential to the establishment of a violation of the law prohibiting filth, insanitation, or decomposition. But it is on the more important health considerations that FDA has concentrated most of its control activities. With the vast numbers of establishments and conditions involved, it hardly has been able to do otherwise. While there have been complaints that the FDA has been too technical or fastidious in its approach, and the preponderance of legal actions too technical or fastidious in its approach, and the preponderance of legal actions appears to have involved seemingly innocuous conditions, in the great majority of cases it appears that FDA's action was motivated by more essential matters. In many instances, the deleterious nature of the offense is of more serious potential than is patent. It is obvious that these conditions breed upon themselves, frequently to the point where real hazards are created. The FDA should not be subject to criticism for following the axiom of "an ounce of prevention," particularly when it lacks the facilities to effect the "pound of cure."

It is clear from the facts set forth earlier in this section that FDA requires a larger force to do really effective work in controlling filth, insanitation, and decomposition. At the present rate of inspection the statistics would indicate that among all food estabilshments any one would be inspected only on an average of once every 60 years. Actually, FDA does much better than that, because of its basic health objectives, and may visit some locations several times a year. Yet it is known that some important food concerns have not been inspected for many years. Since the problem must always be one of selection, some suggestions for improved efficiency are set forth in the recommendations at the conclusion of this section.

The FDA, can, perhaps, more appropriately reevaluate its policies on this point than on any other on this subject. Even if it does so drastically, it is still apparent that its facilities are inadequate properly to cover the industry.

PESTICIDES

In 1954, the Food and Drug Act (sec. 408) was amended to provide protection to the consuming public against pesticide residues which may be used on agricultural commodities during the course of their production. This was required

because of the increasing use of these materials and the substantial evidence of their residual toxicity which would be carried over to the food even after processing. The amendment, in effect, requires a precertification as to the usefulness of a pesticide and thereafter the establishment of tolerances by the FDA for the quantities of the material which may be in or on the food at the time of its processing. The statute contains very involved procedural conditions in an attempt to provide adequate protection for the legal rights of all concerned. Unfortunately, these procedures require the prompt and concentrated attention of the Food and Drug Administration.

Recently, FDA published the required regulations under the statute. While it is too soon to evaluate fully the problems which these and the law will impose on the Administration, it is clear that it will place substantial burdens on its facilities and personnel.

CONCLUSIONS AND RECOMMENDATIONS

There are areas of administration and enforcement where FDA possibly could improve its techniques. While these would serve to improve its scope and coverage of food programs, they would still not permit it to attain the essential protection for which the law was designed. The administration is presently operating on the equivalent of a prewar budget, while the unit volume of foods which it must control has undoubtedly doubled. Meanwhile, by amendments in the law, its responsibilities are probably at least twice those that existed 10 years ago. It seems unreasonable to ask any group to handle a quadrupled task with tools originally made available for one. It is therefore urged that the funds and manpower required to provide adequate coverage of food programs be assured and that provision be made to supply the additional money and manpower needed to effect the specific recommendations listed below.

1. The standard-making procedure is an extremely time-consuming and expensive one, because of the requirements of the law and a desire to protect the interests of affected parties. While it is recognized that these procedures are desirable in the interest of fairness and the preservation of legal rights, every reasonable step should be taken to reduce them to an absolute minimum. To this end, it is recommended that—

Wherever possible, standards should be proposed in substance and form so as to make possible their adoption under the terms of the Hale amendment (sec. 401 (b));

Means should be explored, developed, and practiced to reduce, even at the risk of subsequent litigation, the technicalities and lengths of the hearings;

Standards should be proposed primarily in areas of major significance, and less attention should be directed to areas where there is little controversy;

Standards should be sufficiently flexible to permit of change, not inconsistent with last item above, for the improvement of quality or value, or the introduction of new varieties or forms; and

Enforcement should be advisory at first, and only punitive in flagrant substantial abuses.

2. The complexities of existing standard-making procedures have brought the FDA's efforts, under present budgetaary limitations, practically to a standstill. This should be corrected.

3. Pending the adoption of the proposed amendment providing for the establishment of legal standards for new chemicals in food in cooperation with the manufacturers themselves. it is recommended that the FDA improve its program on chemical additives by—

Fostering optimum cooperation with and from manufacturers so that they will consult with FDA concerning the use of additives before such use;

Publicizing to the industry its recommendations on additives and their use;

Making its standards of "necessary and unavoidable" and "poisonous and deleterious" as realistic and flexible as is consistent with practical health and major economic considerations; and

Concentrating its inspections for additive use on those segments of the food and food chemical industries which have not established an unwavering policy of integrity and responsibility.

APPENDIX

PROGRESS REPORT[1]

[1] This report is one of a series prepared at the request of Congress to be kept informed of program developments and research progress of the National Institutes of Health and its grantees. It should not be cited in lists of publications available on request.

National Institutes of Health, United States Department of Health, Education, and Welfare, Public Health Service, March 1957

EXTERNAL AGENTS IN CANCER CAUSATION

Cancer is an abnormal type of tissue growth which progressively invades, destroys, and replaces neighboring normal tissues. It has the additional characteristic of metastasizing—that is, spreading to distant sites in the body by traveling through the lymph and blood channels and setting up secondary growths.

The question of how such a growth can happen comes to mind immediately. Many cancer investigators believe that cancer starts in the cell. The next logical question is, what causes a normal cell to change to a cancerous one? The efforts that are being made to find answers to this question constitute an important area in cancer research at the present time, and success in these efforts will undoubtedly yield a major key to the control of the disease.

The agents that act on normal cells to transform them into cancer cells are called carcinogens, and the process by which they act is known as carcinogenesis. Some carcinogens are foreign to the host and are therefore external, or extrinsic; others are produced by the host or have a living origin and are internal, or intrinsic. In this progress report some of the present knowledge of external agents in cancer causation is summarized. Studies of cancer-causing agents in the environment and of the cancer-causing process are included.

HISTORICAL BACKGROUND

One of the earliest observations of the relation between external agents and cancer dates back to the 18th century. In 1775, Sir Percival Pott, a London surgeon, described cancer of the scrotum in chimney sweeps and suggested a connection between the accumulation of soot on their bodies and the disease. Two other observations prior to the modern industrial era are noteworthy. In one, cancer of the skin was reported in the early 19th century among workers in copper smelters and tin foundries in Cornwall and Wales, and a relationship was suggested between these lesions and the occupational exposure to arsenic fumes. The other observation concerns an occupational disease of the lungs found among the workers mining cobalt at Schneeberg, in Saxony, Germany, and among those mining uranium at Joachimstal, in Bohemia. In the early 1900's the disease was finally diagnosed as lung cancer.

With the development of the coal-tar industry during the 19th century, an abnormally high incidence of skin cancer was observed in workers in the tar-distillation plants. For many years attempts to prove that cancer could be produced by a chemical substance were fruitless. Finally, in 1915, as a result of the long and patient application of coal tar to the ears of rabbits, two Japanese workers were able to announce the first successful induction of cancer in an animal.

After these pioneer investigations, the next logical step was to find and isolate the carcinogenic (cancer-causing) chemical in coal tar. A group of English investigators set themselves this task in the early 1920's. A decade later, after considerable research, they successfully isolated a compound that produced cancer of the skin when painted on mice. This compound was 3,4–benzpyrene. It is powerfully carcinogenic and is one of the most widely employed carcinogens in experimental cancer research. It is of considerable interest because of its wide distribution. 3,4–benzpyrene has been identified in the soot of industrial cities and in the exhaust of internal combustion engines, in processed rubber, in carbon blacks, petroleum and shale oils, and in the atmosphere. In this connection, it should be mentioned that the extracts of atmospheric dusts are carcinogenic when injected into mice.

Simultaneously with the English workers, an American group under the auspices of the United States Public Health Service engaged in a similar series of investigations. They prepared compounds among the same classes of substances as those studied in England and tested them for carcinogenicity in mice.

The successes of these efforts led to various activities in research on external agents in cancer. Among them are the following:

The study of environmental cancer—that is, the search for other agents in man's environment that might be carcinogenic—in order to become alerted to their potential hazard as cancer producers.

The synthesis and testing for carcinogenic potency of literally thousands of compounds in order to detect, if possible, some fundamental carcinogenic property.

The biochemical study of the mode of action of the external carcinogenic agents.

DIFFICULTIES IN CORRELATING EXTERNAL AGENTS WITH CANCER IN MAN

Since carcinogenesis in man cannot be studied by direct experimentation, other means have been devised to recognize external agents that may be concerned with the production of cancer. Because these means are indirect, the information that they produce cannot in most cases be interpreted as conclusive evidence with respect to human cancer, but must be considered as indicating a possible causal relation.

Epidemiological and statistical surveys

One of the ways of collecting such information consists of epidemiological and statistical surveys. The techniques used in these studies deal with quantitative relationships among the various factors that determine how a disease is distributed in human population groups. For example, the number of cancer cases in a selected group, such as workers in a certain occupation, may be compared with the number of cases in the general population.

An observation that has made such comparisons difficult to correlate is that long latent periods may be involved between the time of exposure and the time of diagnosis of a cancerous condition. Dr. W. C. Heuper, chief of the Environmental Cancer Section of the National Cancer Institute, has listed certain latent periods for various types of cancer. In general, they range from 5 to 30 years and indicate that individual susceptibility (hereditary influences) and differences in the intensity of exposure to the carcinogen probably play important roles.

Epidemiological data have been difficult to interpret also for other reasons. Systems of recording vital statistics vary in different areas of any country. Also, assignment of the cause of death on medical certificates may occasionally be a matter of choice, since the terminal stages of cancer are frequently complicated by other diseases, such as pneumonia.

Nevertheless, epidemiological surveys have definitely correlated cancer in man with exposure to certain agents found in the environment.

Tests with laboratory animals

Agents that are identified by epidemiological correlations as possible cancer producers are then tested on laboratory animals. Difficulties in interpreting information obtained in such tests occur for a number of reasons. The susceptibility of animals to carcinogens differs among species. Therefore, not only the nature of the agent but other factors as well must be considered as influencing the carcinogenic potency of the agent. These include the species of the animal, the dosage, and the mode and length of time of administration. While in general an agent suspected as carcinogenic in man will produce cancer in one or more species of experimental animals, it does not always have this effect. On the other hand, an agent that will produce cancer in an animal may not be a carcinogen for man.

Despite all these qualifying considerations, the important point that investigators bear in mind in evaluating tests with laboratory animals is the following: All environmental agents that are capable of producing cancer in experimental animals when introduced into them by any route are suspected of having a similar effect in man until demonstrated as harmless.

SOME CARCINOGENS IN THE ENVIRONMENT

The environment is a logical research area in which to look for agents that might cause cancer. "Environmental cancer" is cancer produced as a result of exposure to cancer-inducing agents, either at work or in daily living. The different carcinogens that form a part of the environment are practically the only known causes of cancer in man and for this reason have considerable significance.

One reasonable approach to the problem of environmental cancer is to study that segment which can be ascribed to occupation. Some of the known environ-

mental carcinogens never existed in dangerous concentration until the development of certain industrial processes which brought some workers into frequent and close contact with them. As injurious agents have made their appearance with the changing pattern of modern living, "environmental cancers" have developed among exposed people under different circumstances.

The work of Dr. W. C. Heuper and his associates in the field of environmental cancer has been extensive and outstanding. Some of the results of their studies are summarized in the illustration on page 5, which shows the more important environmental carcinogens and the sites they attack in the body. These carcinogens are various types of chemicals and radiations.

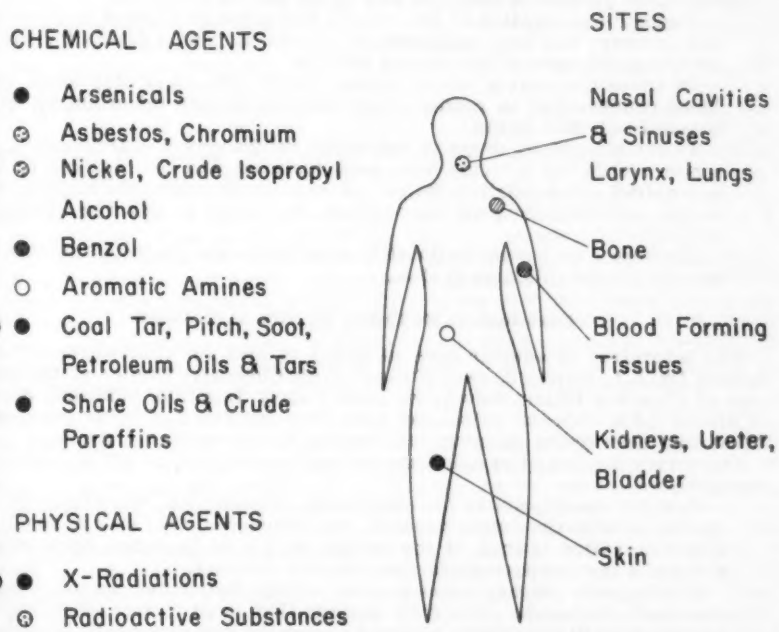
Chemicals

Of the chemicals listed in the illustration, arsenicals cause cancer of the skin. Processing of asbestos, chromium ores, and nickel may be associated with cancer of the respiratory tract. The carcinogenic substances in coal tar, pitch, soot, petroleum and shale oils, and crude paraffins are mostly of the types known as polycyclic hydrocarbons. These are complex molecules consisting of carbon and hydrogen, and they usually produce skin cancer.

The high incidence of lung cancer in recent years has produced increased interest in carcinogens that may be present in the atmosphere. Many studies are being made, and some recent results have suggested the possibility of a relation between lung cancer and air pollutants from gasoline, diesel engine exhausts, and gasoline evaporates.

Fumes of benzol, a chemical widely used in modern industrial processes, may affect the blood-forming tissues and lead to the development of leukemia.

ENVIRONMENTAL CANCER



A few aromatic amines—nitrogen-containing compounds—are included among the carcinogenic agents. Beta naphthylamine, 4-aminodiphenyl, and benzidine have been associated with urinary bladder cancer found among workers in factories handling dyes and rubber antioxidants derived from coal-tar products. The route of exposure to these chemicals is by skin contact, inhalation, and ingestion, but the manner in which they act is not yet known. One way suggested by recent research with laboratory animals is that the body changes them to other compounds that actually cause the bladder cancers.

Physical agents

The carcinogenic physical agents are radiations of various kinds. Solar radiation is the most important natural physical carcinogen. Cumulative exposure to solar radiation produces a relatively high incidence of skin cancer in sailors and farmers. Since it is believed that much of the effect of sunlight in producing skin cancer lies in the ultraviolet region of the spectrum, it is suspected that ultraviolet light is an important causative agent for this type of cancer in man. Studies by Dr. Harold Blum, of the National Cancer Institute, have confirmed the carcinogenic effect of ultraviolet radiation in laboratory animals.

X-rays, radium, and radioactive substances are other carcinogens in this class. They produce leukemia and cancer of the skin, bone, lung, and nasal cavities and sinuses. A well-known example of the carcinogenicity of radium is found in the tragic cases of bone cancer in the young women who during 1917–24 used luminous paints involving radium to paint figures on watch dials and pointed their brushes with their lips. Their cancers appeared 7 to 10 years after exposure. Radiologists have a tenfold greater incidence of leukemia than other physicians and a life span shorter by about 5 years. Another example is the high incidence of leukemia among those survivors of the Hiroshima atom bomb attack who were within 1 mile of the center of the blast. With the prospect of increasing and widespread use of nuclear products, the problem of personnel exposure to radiation sources is becoming more acute.

CANCER-PREVENTION MEASURES

The fact that certain chemicals and radiations are under strong suspicion as cancer-causing agents has led to the wide adoption of cancer-prevention programs. Safe production and handling methods are being developed, and periodic examinations of exposed industrial workers are being instituted.

Some of the preventive measures now in use are the following:

Periodic examination of the cells in the urine of exposed workers in the dye industry has been instituted by several industrial plants for the early detection of cancer of the urinary bladder.

In industrial plants where benzol vapors are an occupational hazard, blood counts—that is, counts of the blood cells—are taken among workers exposed to benzol fumes.

In certain plants, dusts of industrial origin may be carcinogenic. Adequate ventilating systems have been installed and the wearing of masks is required. Also, various devices are used to determine the amount of dust in the breathing zone of the workers, and thus to test the adequacy of ventilation.

Workers who handle radioactive substances are protected against exposure by proper shielding devices.

CHEMICAL CARCINOGENS IN THE LABORATORY

The laboratory is another area in which to look for cancer-causing agents. In 1951 Dr. J. L. Hartwell, head of the Organic Chemistry Section of the Laboratory of Chemical Pharmacology, National Cancer Institute, published a survey of almost 1,300 chemical substances that were suspected of being carcinogenic. These had been tested in many laboratories for carcinogenic activity.

The survey produced the following interesting observations about carcinogenic chemicals:

Roughly one-quarter of the compounds, or about 322, were reported to be carcinogenic in the animals tested. An assumption that may be made from this observation is that, of the compounds yet to be tested, approximately 1 out of 4 may perhaps exhibit carcinogenic potency.

Carcinogenic potency appears to be widely distributed among classes of chemical compounds. The data suggest that more classes of carcinogenic compounds will continue to be found among the new compounds investigated.

Carcinogenic potency has not been correlated with chemical structure. In other words, carcinogenic potency does not appear to be a predictable property of a chemical compound. Hence, investigators must constantly bear in mind that an observed lack of carcinogenic potency implies such a lack only under the conditions of the particular investigation.

The number of compounds tested for carcinogenic potency now runs into the thousands. Dr. Hartwell's compilation is again in process of revision, and it will constitute an important reference source on the carcinogenic potency of many new chemicals.

In general in experimental animals, carcinogenic polycyclic hydrocarbons produce cancers at the site of application—that is, skin cancers—and the aromatic amines produce cancers at sites distant from that of application. For example, some azo dyes are carcinogenic almost exclusively for the liver and bladder; the aminofluorenes and aminostilbenes induce a wide variety of tumors; urethane induces tumors only of the lungs; beta-naphthylamine induces tumors only of the bladder; and nitrogen mustards induce a variety of tumors, particularly of the lungs.

Investigation of chemical carcinogens in laboratory animals serves several purposes. These include the testing of chemicals that have been identified as possible carcinogenic agents in man, the identification of additional carcinogenic chemicals, and the study of the carcinogenic process.

METHOD OF ACTION OF CARCINOGENS

Studies with 2-acetylaminofluorene

One way in which investigators study the carcinogenic process—that is, the manner in which carcinogens react in the tissues of the experimental animal—is by observing the effect of a known carcinogen administered under various conditions.

A well-known carcinogen is 2-acetylaminofluorene, which is one of a class of compounds known as aminofluorenes. This compound was developed as an insecticide. About 15 years ago a study of its effectiveness and toxicity showed that it produced multiple tumors in 3 to 4 months, when incorporated into the diet of rats in concentrations of 0.03 percent or more. The tumors included those of the liver, bladder, breast, and auditory canal.

In recent studies with this compound, Dr. H. P. Morris and his associates in the Nutrition and Carcinogenesis Section of the Laboratory of Biochemistry have found that 2-acetylaminofluorene is carcinogenic both by ingestion and by painting on the skin, and so also are two other compounds related to 2-acetylaminofluorene—2-aminofluorene and 2-nitrofluorene.

Further observation disclosed that the distribution of the tumors in the rat varied according to the nature of the derivative. Thus, aminofluorene induced a certain type of liver tumor, and nitrofluorene had no apparent effect on the liver. The conclusion was that the differences in the types and locations of the tumors suggest that some fundamental carcinogenic property in the fluorene molecule is altered by the nature of the derivative.

In another study, Dr. Morris and his associates found that 2-acetylaminofluorene induces tumors not only in rats and mice but also in dogs after 6 to 8 years of ingestion. The tumors were in the liver and bladder.

In still another study, Dr. Morris and his associates have identified at least 10 hitherto unknown metabolites (breakdown products) of 2-acetylaminofluorene, after it was administered orally. This information provides a clue to the chemical changes that the carcinogen undergoes in the tissues of the host. Such knowledge is important in obtaining indications of the actual form in which the carcinogen may exert its effect and is another step in the accumulation of information necessary for an understanding of the carcinogenic process.

Indication of two steps in carcinogenesis

The first suggestion that there are at least 2 independent steps in carcinogenesis resulted from studies reported about 15 years ago in which a fraction of creosote oil increased the production of skin tumors by various hydrocarbons. A few years later Dr. I. Berenblum studied this phenomenon more extensively while working at the National Cancer Institute on a special fellowship. He found that a single application of the carcinogen, 3,4-benzpyrene to the skin of a mouse may not induce cancer, but if the single application is followed by repeated treatment with croton oil, tumors will develop. Croton oil by itself has no carcinogenic action and, if aplied before the benzpyrene, has no effect. Croton oil appears to be a "promoter of cancer"; its action is gradual, requiring repeated treatment for progression toward tumor formation. Further application of croton oil is unnecessary once a certain stage in tumor production has been reached.

These experiments suggest that the carcinogenic process actually consists of two consecutive actions. The first step may be an induction, or initiating effect, in which one or more cells become potentially malignant. The second step may be a promoting effect, in which the latent cells may be precipitated into the malignant state. The first step may be sudden and irreversible; the second one is gradual and may be accelerated by the promoting agent.

The carcinogenic agent administered in subthreshold amounts need not be a hydrocarbon but can be a source of radiation. Thus, a single exposure of the skin of mice to the moderately energetic beta rays of radioactive thallium, followed by application of croton oil, results in the formation of skin tumors with an average latent period of 3.5 months; animals receiving the same dose of radiation but not treated with croton oil do not develop tumors.

Combination of carcinogens with tissue proteins

A new concept of the first step in carcinogenesis has emerged in the last few years. The carcinogen apparently has the capacity to combine with several proteins found in the cells that constitute the tissues of the host. One of the evidences for this combination is the actual isolation of proteins to which the carcinogenic agents are firmly bound.

The most direct evidence for the combination in the laboratory animal between tissue proteins and carcinogens has come from the work of Drs. J. A. and E. C. Miller, of the University of Wisconsin, whose investigations are supported in part by grants from the National Cancer Institute. The larger bulk of the data dealing with this phenomenon has been derived from the study of aminoazo dye carcinogenesis.

When 4-dimethylaminoazobenzene, a chemical that produces only cancer of the liver, was administered orally to rats, the Millers found that some of the dye was chemically bound to certain of the liver proteins. They found no bound dye in other rat tissues, in which the dye does not induce tumors; very little bound dye in the livers of mice, in which tumors develop slowly; and no bound dye in the livers of resistant species (resistant to cancer of the liver from this chemical), such as guinea pigs, rabbits, cotton rats, and chickens. In another part of the study, they found that the tumor proteins contained no bound dye and were deficient in some of the protein components characteristic of the normal or dye-bound liver.

From these observations of correlations between the bound dyes and carcinogenesis of the liver, the Millers have concluded that the process of binding must be concerned with the carcinogenic action of 4-dimethylaminoazobenzene. They have suggested that perhaps the permanent transformation known as cancer could be the result of an alteration or loss of proteins essential for the control of growth but not for the maintenance of life.

SIGNIFICANCE OF STUDIES OF CANCER CAUSATION

The studies mentioned in this report have shed some light on the cancer-causing process. A few external agents that cause cancer in man are now known, and many more are suspected. Something is known, too, about the way in which external agents react in the host.

The information obtained in such studies is also significant in a broader sense. The environmental cancer studies can help in the prevention of cancer through identification and elimination of hazards. Biochemical studies of the effect of carcinogens on the tissues of experimental animals can help in the development of more effective chemotherapeutic agents for cancer. Such result may stem from the observation that some of the agents that cause cancer—nitrogen mustards, urethane, radiation—can be used to treat it. The interesting possibility arises that the cancer-producing and cancer-destroying processes may somehow be related in their reactions with vital cell constituents.

Thus, the information that increases the understanding of the carcinogenic process can contribute to improvement in cancer prevention and therapy. These are steps toward the goal of the eventual control of cancer.

Mr. DIES. The next witness is Miss Sally Butler, who is appearing for Mrs. R. I. C. Prout, president of the General Federation of Women's Clubs.

STATEMENT OF MRS. R. I. C. PROUT, PRESIDENT, GENERAL FEDERATION OF WOMEN'S CLUBS, PRESENTED BY MISS SALLY BUTLER, LEGISLATIVE CONSULTANT

Miss BUTLER. Thank you, Mr. Dies.

I am glad to come for our organization. I am the legislative consultant for this organization, and I know that we have worked on this specific subject by resolutions since 1950.

The General Federation of Women's Clubs has been concerned with the health and welfare of the people of our country for over 50 years. Because of the work done by this organization, we were credited with being largely responsible for the enactment of the Pure Food and Drug Act of 1906. Dr. Harvey Wiley has openly given us credit. He then was head of the Department.

Since that time, the general federation has endorsed legislation which has strengthened the pure food and drug laws, and this is not the first time we have come to Capitol Hill to voice our support of legislation relative to chemical additives to food products. We testified as early as December 14, 1950, and as late as February 2, 1956.

Women are responsible for the choice and the preparation of most of the food consumed by their families and they therefore have a real concern with the possibilities of human reaction to the chemical additives which are being used.

Due to present-day demands for processed foods which can be quickly and easily prepared and which at the same time retain their attractiveness and freshness, we know that additives are being increasingly used and in varying degrees.

We are aware that some authorities say cancer could be caused by certain chemicals, and we are also aware that other unfavorable reactions are made possible by human consumption of certain chemicals.

We also know that while it might be safe to use a small quantity of such chemicals, there is always the possibility that in a variety of foods served at the same meal, if some chemical was used in more than one item at that meal or on the same day, it would be possible to get an overdose which would be harmful to the consumer.

We feel that the Government has a great responsibility in this matter to protect the health of the people, not only from cancer but also from any other unfavorable reaction. Therefore, we urge this Congress to pass a bill that does not limit its responsibility to preventing cancer alone.

We realize additives sometimes make the item of food look more attractive; hence more salable. Or they may help the producer sell the food because of some special advertising. We know additives are used in bread to keep it softer—we have objected to this because it can mislead or deceive the purchaser into thinking they are buying fresh bread when in fact it has been baked quite some time.

We urge that you pass legislation that uses every possible precaution to protect the consumer. It is your responsibility to protect the public by requiring that additives be properly tested for whatever time necessary to determine whether it is injurious for human beings to consume over a prolonged time.

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We urge you to require that food with such additives be labeled so that the consumer who might be allergic to certain chemicals could be aware that the food contained such chemicals.

We, the women of the General Federation of Women's Clubs, ask you, our voices in Congress, to pass a bill which will prohibit the use of chemical additives in food that has not been adequately tested to establish that they will not injure the consumer.

Mr. DIES. Thank you very much.

Do you have any questions?

Mr. LOSER. Nothing at all, except to express my appreciation to this fine lady for her appearance here, and the very fine statement that she has presented.

Miss BUTLER. Thank you, Mr. Loser.

Mr. DIES. Dr. Neal, do you have any questions?

Mr. NEAL. I would only add to my colleague's expression here by saying that we fully appreciate the great strides the women have made, and their contribution in all walks of life during the past century.

Miss BUTLER. Thank you very much, sir. The women are really interested, as you know.

Mr. DIES. Thank you very much.

The next witness is Mr. Jack T. Jennings, of the Cooperative League of the United States of America.

STATEMENT OF JACK T. JENNINGS, ASSISTANT DIRECTOR, WASHINGTON OFFICE, COOPERATIVE LEAGUE OF THE UNITED STATES OF AMERICA

Mr. JENNINGS. Thank you, sir.

Mr. DIES. Mr. Jennings, will you identify your organization, or do you identify it in your statement?

Mr. JENNINGS. Yes, sir; I do have a short statement, Mr. Chairman. Would you wish that I read the whole thing?

Mr. DIES. No; I think not. You mean in identification of your organization?

Mr. JENNINGS. No; the whole statement.

Mr. DIES. Would you not rather summarize it and place your statement in the record?

Mr. JENNINGS. I can summarize it and include it in the record.

Mr. DIES. Just let me ask you, what is the Cooperative League?

Mr. JENNINGS. The Cooperative League is a national federation of consumer, supply, and service cooperatives. It includes some 13 million people who are affiliated, in one way or another, with various cooperatives, which in turn are members of the Cooperative League.

Mr. DIES. In other words, your organization is sort of the clearinghouse for a number of cooperative leagues?

Mr. JENNINGS. That is right.

Mr. DIES. Sort of a loose federation.

What service do you perform?

Mr. JENNINGS. We perform educational services, including film, literature, and we have a legislative office here in Washington. Our main headquarters are in Chicago.

Mr. DIES. They pay dues to your organization or contribute to the support of your organization?

Mr. JENNINGS. That is right.

Mr. DIES. But you actually have no membership in your organization other than the cooperative organizations?

Mr. JENNINGS. That is right, except a few individuals.

Mr. DIES. Now proceed with your summary, if you will.

Mr. JENNINGS. Needless to say, we appreciate the opportunity to appear before your committee, as we have many times past. We believe that the Congress has a very deep responsibility in this food-additive program.

We realize that these ready-made, partially cooked meals which are used more and more each day, lend themselves to a wider use of certain additives, certain preservatives, and other means of making the food attractive and keeping it in consumable shape, so that it is readily available to the housewife with the least amount of preparation.

Mr. DIES. I think we all are familiar with that need.

Mr. JENNINGS. That is right.

Mr. DIES. And that is our chief concern. What do you recommend? What do you think should be done about it?

Mr. JENNINGS. Well, sir, at the end of my statement I have a few recommendations. I have studied the various bills which are before the committee.

I should say at the outset, I am not a lawyer, so I cannot get into the legal phase of the thing, but we believe that any bill which is recommended by this committee should include, first of all, that there be some control over these chemicals and other additives which are put into our foods.

Mr. DIES. All the bills provide for that.

Mr. JENNINGS. That is right. I have said that is No. 1.

No. 2, there should be no "grandfather clause," so that any food additive can be checked from time to time. We remember the story of Agene, which had been approved at one time, and then later on found not to be a good substance.

We think that H. R. 7798 makes a very clear provision in this respect. Some of the other bills have them incorporated, which I did not detect because I do not have that legal mind.

No. 3, is that the Food and Drug Administration and the Secretary of the Department of Health, Education, and Welfare, should weigh each additive in relation to all others in its total effect on the human body. This is what the lady before me mentioned.

In other words, additives A, B, and C, each may be harmless in itself, but taken together may be harmful.

H. R. 6747 seems to cover this, and H. R. 7798 partially covers this provision.

Then, No. 4, besides the use of the chemicals for preservation, other processes should be considered which might cause harmful effects. Among these is radioactive radiation.

Other types of radiation and other means of preservation may be perfected. Control of these should be inherent in the bill. H. R. 8112 and H. R. 7798 seem to make adequate provision in this respect. H. R. 6747 makes reference to this type of radiation.

And No. 5, an additive should be beneficial to the consumer. Unless food is enhanced in flavor, nutrition, or otherwise better preserved by an additive, it should not be used. Only H. R. 7798 provides that

an additive must "serve a purpose which will be useful to the consuming public."

Another one, the Food and Drug Administration and the Secretary of the Department of Health, Education, and Welfare should have the right to regulate food additives after proper examination of findings.

All the bills under present consideration seem to make this provision.

The Secretary, however, should compile a list of chemicals and processes, which should be revised and amended, as necessary, for the benefit of industry and the consuming public. The list should include approved chemicals and processes, those which are known unsafe, and those which are questionable. H. R. 366 partially covers this provision.

The right of an applicant to appeal should not be taken to the courts. We approve the procedure proposed in H. R. 7798, which puts the problem in the hands of experts. Very few cases are likely to get to the appeal stage.

The burden of proof as well as the burden of appeal should be placed on the manufacturer or user of an additive. No legislation should be equipped with built-in loopholes which will give an additive maker or user the right to continue to use the public as guinea pigs.

Those are our recommendations.

We, as I said, have not designed language for a bill.

Mr. DIES. I think we understand from your conclusions your position on these bills. We thank you.

Do you have any questions?

Mr. LOSER. None at all.

Mr. DIES. Do you have any questions, Dr. Neal?

Mr. NEAL. I would like to ask the gentleman, at the bottom of page 1 and the top of page 2, you refer to a bread softener. What is the chemical additive used by bakers to soften bread, to keep it soft?

Mr. JENNINGS. As I recall, before the bread standards were adopted, it was one of the—it was a mono- or diglyceride.

Mr. NEAL. What?

Mr. JENNINGS. Mono- or diglyceride, or one of the so-called softeners which had been used in both bread and ice cream.

Now, whether the standards outlawed those chemicals, I am not sure. It seems to me they did.

Mr. NEAL. So far as you know, they have not been proved to be deleterious?

Mr. JENNINGS. They were questionable.

Mr. NEAL. They are still questionable?

Mr. JENNINGS. Yes.

Mr. NEAL. That is all. Thank you.

Mr. DIES. Thank you, sir.

Mr. JENNINGS. Thank you very much.

(Mr. Jennings' prepared statement is as follows:)

STATEMENT OF JACK T. JENNINGS, ASSISTANT DIRECTOR, WASHINGTON OFFICE, COOPERATIVE LEAGUE OF THE UNITED STATES OF AMERICA

Mr. Chairman and members of the committee, my name is Jack T. Jenninga. I am assistant director of the Washington office of the Cooperative League of the United States of America.

The Cooperative League is a national federation of consumer, supply, and service cooperatives. Through one or another of our member organizations, 13 million of the United States families who own co-ops are represented in the Cooperative League. These 13 million families represent the largest group of organized consumers in the United States.

We appreciate the opportunity to appear here in support of certain controls over food additives. We believe that it is most important to consumers today, when so much of our foods are processed for quick readiness for the table, that they be free of dangerous chemicals or other additives. America seems to be on the run. The housewife spends fewer hours in the kitchen. The demand for ready meals, all packaged in attractive wrappings, is increasing greatly. If she purchases carefully, the housewife needs not even dirty her dishes and silverware—much less her pots and pans—for the food comes in generous helpings on disposable plates requiring only heating.

This modern era which portends even greater timesaving for cooks of the future has brought about a whole new concept in food preparation and merchandising. Already we have seen a number of things happen which have not necessarily been in the interest of the consumer.

Grandmother used to bake bread once or twice a week. The bread was made of locally milled flour and other health-building ingredients. It was soft only while it was oven warm. Nobody objected to hard bread until the commercial bakers took over. Then they educated grandmother and others that hard bread was stale. Fresh bread was soft. But they didn't tell grandmother they could fool her a bit by adding something to the bread to keep it soft for many days. What they added was not necessarily good for grandmother, but she didn't know the difference.

They pulled the wool over her eyes, too, when they convinced her that real white bread was better. They didn't tell her that in order to get it white, they used a poisonous substance which gave dogs fits. They didn't tell her they removed some of the finest nutritional qualities to make the bread white. What they were doing was lowering the quality of a basic food while claiming they were making a better looking, better tasting product.

The same situation may apply to many other foods. Those who manufacture foods are always looking around for cheaper ingredients than the food itself. We recall the strawberry-preserves manufacturer who was hauled before officials who asked him why there was only one strawberry to the jar. It was cheaper not to use strawberries for the jam. We don't think grandmother would have appreciated this man's recipe.

As consumers, we have been fooled quite a bit. We are still being fooled, for there are some 150 food additives that have not been tested by Food and Drug Administration but are present in food we eat today. We are not sure, when we buy our daily requirements, whether we are paying for wholesome, nutritious food or whether we are paying high prices for sugar extenders, butter and shortening substitutes, and imitation coloring and flavor.

For some reason, we have been educated to the idea that there should be a certain amount of pride in making something that really isn't what it is. Like strawberry preserves without any strawberries. Or chicken salad without any chicken. There's something wrong with this philosophy. It helps those who really want to use cheap substitutes to give us the business.

We don't propose to return to the "good old days" but we do think there is some merit in taking stock of our present "progress." Since mother and grandmother are not spending much time in the kitchen, we've got to depend upon someone else's integrity. You could rest assured that grandmother would not put anything in food that might make us ill—or was not good for us—if she could help it. She cooked beans all day so they would be tender and delicious. Now they come in a can probably with a generous amount of softeners and imitation meat and flavoring.

As consumers, we should know what we are eating. And those of us who cannot distinguish between good and bad chemical names should be given some help. We went through this a few years ago before another committee where we pointed out that animal feed formulas are disclosed on a bag of feed, but the secret ingredients of food we eat have been carefully guarded. In co-ops we try to give the consumer all the information possible so that she will know what's inside the can, bottle, or package.

There was a time when farmers bought feed sight unseen. Co-ops, owned and controlled by farmers, decided farmers had a right to know what was in the bag. Co-ops began to list the ingredients and the formula for hog, chicken, and other feeds. The industry then said such a program would put old line feed

manufacturers out of business. Now much of the industry is following the co-op open formula plan—and to our knowledge, not a single open and above-board maker has suffered. Feed standards are much higher as a result.

The point we are trying to make is this: If the housewife were informed as to certain additives in certain foods, she might not choose to buy them. At least a part of this food additive program might then be solved. Additive manufacturers might not be anxious to peddle their wares if they know that an informed housewife could find the additives listed prominently on a food product label.

Probably some of the things we have mentioned cannot be incorporated in the legislation being considered here. Nonetheless the fact remains that we are faced with a broader problem than just policing the use of certaind food additives.

We cannot pose as experts before your committee on the food additive issue. We suggest that the uppermost thought in considering these bills is consuumer protection. We leave it to the experts to incorporate this protection in effective language. We believe final legislation should include the following provisions:

1. Chemicals and other substances used in or proposed to be used in food which have a questionable or hazardous effect on the human body should be outlawed. In our opinion, that is the objective of the bills being considered here.

2. There should be no grandfather clause to exempt any food additive now in use. Provision should be made for review of any substance, even though it has been previously approved. Only H. R. 7798 makes this provision clear.

3. Food and Drug Administration and the Secretary of the Department of Health, Education, and Welfare should weigh each additive in relation to all others in its total effect on the human body. Additives A, B, and C each may be harmless, while normal consumption of all three in combination may be harmful. The cumulative effect of various substances should also be considered. H. R. 6747 covers and H. R. 7798 partially covers this provision.

4. Besides the use of chemicals for preservation, other processes should be considered which might cause harmful effects.

Among these is radioactive radiation. Other types of radiation and other means of preservation may be perfected. Control of these should be inherent in the bill. H. R. 8112 and H. R. 7798 make adequate provision in this respect. H. R. 6747 makes reference to radiation.

5. An additive should be beneficial to the consumer. Unless food is enhanced in flavor or nutrition, or otherwise better preserved by an additive, it should not be used. Only H. R. 7798 provides that an additive must "serve a purpose which will be useful to the consuming public."

6. Food and Drug Administration and the Secretary of the Department of Health, Education, and Welfare should have the right to regulate food additives after proper examination of findings. All the bills under present consideration make this provision.

7. The Secretary should compile a list of chemicals and processes which should be revised and amended as necessary for the benefit of industry and the public. The list should include approved chemicals and processes, those which are known unsafe, and those which are questionable. H. R. 366 partially covers this provision.

8. The right of an applicant to appeal should not be taken to the courts. We approve the procedure proposed in H. R. 7798 which puts the problem in the hands of experts. Very few cases are likely to get to the appeal stage.

9. The burden of proof as well as the burden of appeal should be placed on the manufacturer or user of an additive. No legislation should be equipped with built-in loopholes which will give an additive maker or user the right to continue to use the public as guinea pigs.

Producers and users of food additives can present an impressive show. They can hire experts who serve to protect the industry. We repeat, that out of all the testimony from the parade of witnesses, the consumer interest is paramount.

The consumer interest is the public interest. The Cooperative League respectfully urges your insistence that any food additive legislation will assure consumer protection.

Thank you.

Mr. DIES. That concludes all our witnesses for today, and the subcommittee will stand adjourned subject to call.

(Whereupon, at 11:05 a. m., the subcommittee adjourned, subject to the call of the Chair.)

FOOD ADDITIVES

TUESDAY, AUGUST 6, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommitee met, pursuant to recess, at 10 a. m., in room 1334 New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. The committee will please be in order.

This morning the Subcommittee on Health and Science is fortunate indeed to welcome a panel of outstanding scientists and experts to discuss for the benefit of members of the subcommittee and those members of the full committee who are able to attend, the scientific background with regard to the testing and evaluating of the safety of chemical additives. The subcommittee is greatly indebted to Dr. Detlev Bronk, President of the National Academy of Sciences, Dr. S. D. Cornell, executive officer of the National Academy of Sciences, and Dr. Paul E. Johnson, executive secretary of the Food Protection Committee of the National Academy of Sciences, for their cooperation in suggesting the chairman and selecting the members of this panel.

I do not want to consume any valuable time this morning with an opening statement. I merely want to say that the Committee on Interstate and Foreign Commerce is proud of the fact that it has pioneered successfully with the panel method of discussing complex and controversial scientific issues.

I hope that the discussion today and tomorrow will greatly assist the subcommittee in getting a clearer picture of the problems involved in testing and evaluating the safety of chemical additives.

The procedure that we might follow for the next 2 days might well be about the same as that followed by the Salk vaccine panel in the last Congress. First, the chairman and the members of the panel will introduce themselves for the benefit of the record and give briefly their educational background and their particular qualifications in the field of chemical additives.

This will be followed by brief statements from the chairman and each member of the panel in which they will outline the specific aspects which they care to contribute to this discussion.

Following each statement, we will have a brief question period during which, under the direction of the panel chairman, other members of the panel will be able to ask questions of the speaker. Of course, members of the committee will also want to ask questions and I hope they will use this opportunity freely so that they will gain a

better understanding of the problems involved. This method proved rather successful in the case of the Salk vaccine panel and I hope it will work in this instance.

Finally, I want to stress that the chairman and the members of the panel are here at the invitation of the committee and they are here at their own expense.

We of the committee feel that the panel is rendering an outstanding public service and we greatly appreciate the sacrifice which the chairman and members are making. We hope that they will be repaid for their public service, at least in part, by the benefits which we hope will come to the American people from the enactment of chemical additive legislation now pending before this committee.

At this time I would like to introduce the chairman of the panel, Dr. William Darby. And Dr. Darby, we will turn the meeting over to you at this point.

(At the request of the subcommittee, the following documents were submitted:)

CURRICULUM VITAE OF PROF. H. E. CARTER

(Head, Department of Chemistry and Chemical Engineering)

Born in Indiana in 1910. Bachelor of arts DePauw University, 1930; master of arts, University of Illinois, 1931; doctor of philosophy, University of Illinois, 1934. Held following positions, University of Illinois; instructor, 1933–35; associate, 1935–37; assistant professor, 1937–43; associate professor, 1943–44; professor, 1944——; head, department of chemistry and chemical engineering, 1954——.

Member:

American Chemical Society.
American Society of Biological Chemists (president, 1956–57).
American Institute of Nutrition (secretary, 1945–48).
American Association for the Advancement of Science.
National Academy of Sciences (1953——).
National Research Council:
(*a*) Division of chemistry and chemical technology, member, executive committee, 1950–55; 1957–58.
(*b*) Food protection committee of division of biology and agriculture (1955——).
Editorial board, Journal of Biological Chemistry.
Editorial board, Journal of the American Chemical Society.
Biochemical preparations, editorial board; editor-in-chief, volume I.

Research activities:

Synthesis, metabolism, nutrition of amino acids.
Extensive studies in the antibiotic field—isolation, structure, biosynthesis (penicillin, streptomycin, streptothricin, neamine, neomycins).
Lipide chemistry and metabolism—soybean, corn, and other plant phosphatides; lipides of brain and nervous system.

CURRICULUM VITAE OF WILLIAM J. DARBY

Training:

1937: M. D., University of Arkansas;
1941: M. S. in biological chemistry, University of Michigan;
1942: Ph. D. in biochemistry, University of Michigan.

Positions:

1942–43: Special fellow in nutrition of the international health division of the Rockefeller Foundation, department of medicine, Vanderbilt University School of Medicine.
1943–44: Director of medical nutrition, North Carolina State Board of Health, assigned to Duke University School of Medicine; instructor in preventive medicine, Duke University; assistant research professor in nutrition, School of Public Health, University of North Carolina.
1944–46: Assistant professor of biochemistry, assistant professor of medicine, Vanderbilt University School of Medicine.
1946–48: Associate professor of biochemistry, Vanderbilt University School of Medicine.
1948——: Professor of biochemistry, assistant professor of medicine and director of the division of nutrition, Vanderbilt University School of Medicine.
1948——: Member of the Council on Foods and Nutrition, American Medical Association.
1948–53: Member of Study Section on Biochemistry and Nutrition (1948–51), Chairman, Metabolism and Nutrition Study Section (1951–53), USPHS, Division of Research Grants and Fellowships.
1949——: Head, department of biochemistry and director of division of nutrition, Vanderbilt University School of Medicine; member of the Food and Nutrition Board, National Research Council (Executive Committee, 1955——).
1950——: Member, committee on food protection, chairman, 1954——.
1949–54: Member of the committee on chemicals introduced in foods, a committee of the food and nutrition section, American Public Health Association.
1950——: Member (chairman) of the advisory board of the Institute of Nutrition for Central America and Panama; Member of the World Health Organization Expert Panel on Nutrition, WHO consultant on nutrition in Yugoslavia, Austria, Egypt, Southern Rhodesia, Basutoland, Guatemala and other Central American countries, and Panama.
1954–57: Member, FAO/WHO Joint Expert Committee on Nutrition, Chairman, 1958.
1956: Member (Chairman) First Joint FAO/WHO Expert Committee on Food Additives.
1957——: Member, Board of Scientific Counselors, National Institute of Arthritis and Metabolic Diseases, NIH.

Scientific societies:

American Chemical Society (division of biological chemistry).
American Institute of Nutrition (vice president, 1956–57).
American Public Health Association (member governing council, 1957——).
American Medical Association.
American Society of Biological Chemists.
Society for Experimental Biology and Medicine.
The Nutrition Society (British).
Southern Society for Clinical Research (vice president, 1948).
American Federation for Clinical Research.
Society for Clinical Investigation.
Association of American Physicians.
American Association for the Advancement of Science.

CURRICULUM VITAE OF JOHN H. FOULGER, DIRECTOR OF MEDICAL RESEARCH, E. I. DU PONT DE NEMOURS & CO., INC., WILMINGTON, DEL.

Education:
Bachelor of science, with first class honors in chemistry, University of London, England, 1920.
Master of Science in Chemistry, University of London, 1922.
Doctor of philosophy in biochemistry, University of Cincinnati, Cincinnati, Ohio, 1924.
Doctor of medicine, University of Cincinnati, 1930.

Appointments:
Demonstrator in chemistry, University of London, 1921–23.
Fellow in biochemistry, University of Cincinnati, 1923–24.
Instructor in biochemistry, University of Cincinnati, 1924–27.
Assistant professor of biochemistry, University of Cincinnati, 1927–28.
Assistant professor of pharmacology, University of Cincinnati, 1928–31.
Associate professor of pharmacology, University of Cincinnati, 1931–35.
Senior toxicologist, Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours & Co., Inc., Wilmington, Del., 1935–38.
Director of Haskell Laboratory, 1939–52.
Director of medical research, E. I. du Pont de Nemours & Co., Inc., 1952 to present.

Memberships—Societies:
Fellow:
American College of Physicians.
American Academy Occupational Medicine.
American Academy Compensation Medicine.
Industrial Medical Association.
American Association for the Advancement of Science.
Member:
American Medical Association.
Medical Society of Delaware.
New Castle County Medical Society (Delaware).
American Public Health Association.
American Industrial Hygiene Association.
American Chemical Society.

Membership—National and State committees:
American Standards Association:
Z–37: Allowable concentrations of toxic dusts and gases; Z–62: Uniform industrial hygiene standards; Z–66: Hazards to children.
Association of Economic Poison Control Officials: Toxicity and antidotes committee.
State of Delaware:
State board on mental health training and research.
Advisory council of the Wilmington Civil Defense Organization.
Field committee, Delaware Mental Health Association.
Industrial Medical Association:
Toxicology committee.
American Standards Association liaison committee of the Industrial Medical Association.
Manufacturing Chemists' Association, Inc.:
Chemicals in foods committee.
Labels and precautionary information committee.
Medical advisory committee (chairman).
Synthetic Organic Chemicals Manufacturers' Association: Chemical additives committee.
National Paint, Varnish & Lacquer Association, Inc.:
Toxic materials committee (chairman).
The model labeling committee.

Publications: Numerous reports on research in chemistry and medicine. Articles on toxicology, medical control of industrial exposure to chemicals and preventive medicine in the chemical industry.

Medical licensure: Licensed to practice medicine in the States of Delaware and Ohio.

Specialty certification: Certified in occupational medicine by American Board of Preventive Medicine, Inc.

CURRICULUM VITAE OF W. C. HUEPER, M. D.

1894: Born Schwerin, Germany.
1920: Medical degree, University of Kiel, Germany.
1924: State Board Examination and License, Illinois.
1929: Naturalized 1929, Illinois.
1920–21: Assistant physician, Evangelisches Diakonissenkrankenhaus, Witten; surgery.
1921–23: Assistant physician, Pathological Institute, Auguste Viktoria Krankenhaus, Berlin.
1924–30: Pathologist and director of laboratories, Mercy Hospital, Chicago, Ill.; associate professor of pathology, Loyola University School of Medicine, Chicago, Ill.
1930–33: Chief pathologist, Cancer Research Laboratories, University of Pennsylvania, Philadelphia; pathologist, American Oncologic Hospital, Philadelphia.
1934–38: Assistant director and pathologist, Haskell Laboratory of Industrial Toxicology, Du Pont Co., Wilmington, Del.
1938–48: Assistant director and principal pathologist, Warner Institute for Therapeutic Research, New York.
1948—: Chief, Environmental Cancer Section, National Cancer Institute.

Professional offices and memberships:

Charter member and first president, American Society for the Study of Arteriosclerosis.
Fellow, New York Academy of Science (honorary).
Fellow, American Association for the Advancement of Science (honorary).
Chairman, committee on cancer prevention, International Union Against Cancer.
Specialist, certified by the American Board of Pathology and by the American Board of Preventive Medicine.
Consultant in environmental cancer, United States Department of Labor, Bureau of Employees' Compensation.
Adviser to Office of Surgeon General of the Army on cancer aspects of irradiated foodstuffs.
Adviser on cancer aspects to air-pollution program, Public Health Service.
Cochairman, symposium on potential cancer hazards from chemical additives and contaminants to foodstuffs. International Union Against Cancer. Rome, Italy, August 10–15, 1956.

SELECTED LIST OF PUBLICATIONS PERTAINING TO ENVIRONMENTAL HEALTH AND CANCER HAZARDS FROM FOOD ADDITIVES AND RELATED MATERIALS

1. Über die hostologischen Veränderungen in menschlichen Gewebe nach Injection von Paraffin. Frankfurt. Ztschr. f. Path. 29: 268–286, 1923.
2. Effects of Neoarsphenamine on Spontaneous Breast Tumours of Mice. Hueper, W. C. and Shigamitsu, I., Am. J. Cancer, 17: 106–115, 1933.
3. Leukemoid and Leukemic Conditions in White Mice with Spontaneous Mammary Carcinoma. Folia haemat. 52: 167–178, 1934.
4. Cancer of the Urinary Bladder in Workers of Chemical Dye Factories and Dyeing Establishments: A Review. J. Ind. Hyg. 16: 255–281, 1934.
5. Fatal Ethylene Dichlorid Poisoning. Hueper, W. C. and Smith, C., Am. J. M. Sc. 189: 778–784, 1935.
6. Toxicological Aspects of Mercury and Mercury Compounds. Medical Handbook, DuPont Company, Haskell Laboratory, 1935.
7. Toxicological Aspects of Fluorine Compounds. Medical Handbook, Du Pont Company, Haskell Laboratory, 1935.
8. Experimental Production of Bladder Tumors in Dogs by Administration of Beta-Naphthylamine. Hueper, W. C., Wiley, F. H. and Wolfe, H. D. J. Indust. Hyg. & Toxicol. 20: 46–84, 1938.
9. Experimental Studies in Cardiovascular Pathology. IV. Methyl Cellulose Atheromatosis and Thesaurosis. Arch. Path. 33: 1–17, 1942.
10. Macromolecular Substances as Pathogenic Agents. Arch. Path. 33: 267–290, 1942.
11. Morphological Aspects of Experimental Actinic and Arsenic Carcinoma in the Skin of Rats. Cancer Res. 2: 551–559, 1942.
12. Experimental Studies in Cardiovascular Pathology. VI. Pectin Atheromatosis and Thesaurosis in Rabbits and in Dogs. Arch. Path. 34: 883–901, 1942.

13. Experimental Studies on the Therapy and the Prevention of Degenerative Vascular Diseases. II. The Effects of Several Detergents on Experimental Cholesterol Atheromatosis of Rabbits. Arch. Path. 38: 381–391, 1944.

14. Arteriosclerosis. A General Review. Arch. Path. 38: 162, 245, 350, 1944; 39: 51, 117, 187, 1945. pp. 133.

15. Experimental Studies in Cardiovascular Pathology. XI. Thesaurosis and Atheromatosis Produced in Dogs by the Repeated Intravenous Injection of Solutions of Sodium Cellulose Glycollate. Am. J. Path. 21: 1021–1029, 1945.

16. Environmental and Occupational Cancer. A Monograph. Supplement 209. Public Health Reports, 1948. 69 pp.

17. Chemicals in Foods and Cosmetics. Proc. House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, House of Representatives, 82d Congress, 2d session, United States Government Printing Office, Part 3, 1952.

18. Experimental Studies in Metal Cancerigenesis. II. Experimental Uranium Cancers in Rats. Hueper, W. C., Zuefle, J. M., Link, A. M. and Johnson, M. G., J. N. C. I. Reprint No. 417. 13: 291–305, 1952.

19. Carcinogenic Studies on Adsorbates of Industrially Polluted Raw and Finished Water Supplies. Hueper, W. C. and Ruchhoft, C. C., Arch. Indust. Hyg. & Occup. Med. 9: 488–495, 1954.

20. Recent Developments in Environmental Cancer. A Review. Arch. Path. 58: 360–399; 475–523; 645–682, 1954.

21. Considerations for the Selection of Chemicals for Carcinogenic Screening. Arch. Ind. Hyg. & Occup. Med. 11: 494–504, 1955.

22. Medicolegal Aspects of Cancer. Am. J. Clin. Pathol. 25: 116–125, 1955.

23. Pathogenesis of Atherosclerosis. Am. J. Clin. Pathol. 26: 559–578, 1956.

24. Potential Role of Non-Nutritive Food Additives and Contaminants as Environmental Carcinogens. Arch. Pathol. 62: 218–249, 1956.

25. Experimental Carcinogenic Studies in Macromolecular Chemicals. I. Neoplastic Reactions in Rats and Mice After Parenteral Introduction of Polyvinyl Pyrrolidones. Cancer. 10: 8–18, 1957.

26. Polycyclic Aromatic Hydrocarbons in Coffee Soots. Kuratsune, M. and Hueper, W. C. J. N. C. I. In press.

27. Benzo[a]pyrene content of certain pyrogenic materials. Kuratsune, M. J. N. C. I. 16: 1485–1496, 1956.

28. Determination of Polycyclic Aromatic Hydrocarbons in Oysters Collected in Polluted Water. Cahnmann, H. J. and Kuratsune, M., Anal. Chem. 29: 1312–1317, 1957.

BOOKS

1. Occupational Tumors and Allied Diseases. Springfield, Illinois, C. C. Thomas, 1942, pp. 890.

2. Degenerative Vascular Diseases in Clinical Cardiology. Editor: Franklin C. Massey, M. D. Baltimore, Maryland, Williams & Wilkins Co., 1953, chapter 15, pp. 545–613.

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5. A Quest Into the Environmental Causes of Cancer of the Lung. Pub. Health Monog. No. 36, Department of Health, Education, and Welfare, PHS Publication. No. 452, USGPO, Washington, 1955, 54 pp.

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8. Medicolegal Aspects of Cancer in Medicolegal Problems for Lawyers. Editor: Marshall Houts. Springfield, Ill. C. C. Thomas. In press.

9. Prevention of Cancer in Treatment of Cancer and Allied Diseases. Editors: Pack and Ariel, 2d edition. Publisher Hoeber-Harper, New York. In press.

Curriculum Vitae of Harvey K. Murer

HARVEY K. MURER, General Foods Corp., 250 Park Avenue, New York, N. Y.; chemistry: Tacoma, Wash., May 23, 1911; m. 1939; c. 1, bachelor of science, State College Washington, 1933; Harvard, 1936–37; Northwestern, 1939. Anal. chemist, Experiment Station, State College Washington, 1933–34, research chemist, department of dairy husbandry, 1934–39; fellow biochemistry, Northwestern, 1939; Tennessee, 1939–40; project leader, General Foods Corp., 1941–45; laboratory director, 1945–48, staff technologist, research and development department, 1948–50, manager, Central Laboratories,[1] 1950——; biochemistry, physiology, food processing, research management.

Curriculum Vitae of Freedus N. Peters, Jr.

Born: Kansas City, Mo., January 30, 1897; bachelor of arts, University of Missouri, 1920; master of arts, University of Missouri, 1922; doctor of philosophy (organic chemistry) University of Wisconsin, 1925.

Assistant city chemist, food and dairy laboratories, Kansas City, Mo., 1918–19.

Research chemist, the Miner laboratories, Chicago, 1925–31.

Technical division, the Quaker Oats Co., 1931–36; director of research, The Quaker Oats Co., 1936–46; vice president in charge of research, the Quaker Oats Co., 1946 to present.

Member: American Chemical Society; American Association for the Advancement of Science Sigma Xi; Institute of Food Technologists; American Association of Cereal Chemists; Scientific advisory committee, Nutrition Foundation, 1946——; Board of directors, Research & Development Associates, Food and Container Institute for the Armed Forces, 1951–54; Industry committee, liaison panel of Food Protection Committee, 1955–57; chairman, 1956; food and nutrition board, National Research Council, 1957——.

Author: The Furans (Reinhold Publishing Co., N. Y. 1953); Numerous articles on food additives, food and drug laws for various professional journals.

Curriculum Vitae of M. H. Seevers, Ann Arbor, Mich.

Maurice Harrison Seevers, Ph. D., M. D., department of pharmacology, University of Michigan Medical School, Ann Arbor, Mich. Home address: 620 Oxford Road, Ann Arbor, Mich. Date of birth: October 3, 1901, Topeka, Kans.

Education:

Washburn College (Topeka, Kans., 1920–24 (bachelor of arts).

University of Chicago, 1924–28 (doctor of philosophy, pharmacology).

University of Chicago (Rush Medical) (4-year certificate) 1930; (M. D.) 1932.

Internship, University of Wisconsin General Hospital 1930–32.

Appointments:

Assistant professor, pharmacology, Wisconsin, 1930–34.

Associate professor, pharmacology, Wisconsin, 1934–42.

Visiting associate professor, pharmacology (summer, 1941), Chicago.

Professor of pharmacology and chairman of the department of pharmacology, University of Michigan Medical School, 1942——.

Associate dean, University of Michigan Medical School 1947–50.

Memberships:

American Society of Pharmacology and Experimental Therapeutics (1930——, president, 1946, 1947; Board of Publication Trustees, 1948 (chairman) 1949——.

American Physiological Society (1933——), editorial board, Physiological Reviews, 1943–51.

Federation of American Societies of Experimental Biology, executive committee, 1946, 1947 (chairman), 1948.

Society for Experimental Biology and Medicine, editorial board, Proceedings, 1944–49; council, 1950——.

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[1] Name and location changed from Central Laboratories, Hoboken, N. J., to Research Center, Tarrytown, N. Y.

American Medical Association (fellow), vice chairman, section on experimental medicine and therapeutics, 1951–52; chairman 1952–53; member council on pharmacy and chemistry, 1952– —.
American Chemical Society, medicinal chemical division; editorial board, Medicinal Chemical Symposium, 1951– —.
Conference on Neuropharmacy, Josiah Macy Jr. Foundation 1954–59.

Consultant positions:
Consultant, Research and Development Board, Department of Defense 1952– —.
Consultant in pharmacology, Pharmacology Study Section, National Institutes of Health, 1944–48.
Member, Board of Scientific Counselors, National Heart Institute National Institutes of Health 1957– —.
National Research Council
Committee on Drug Addiction and Narcotics, 1946– —.
Subcommittee Anesthesiology (Committee on Surgery), 1948–57.
Ad Hoc Committee for Review of Chemical-Biological Coordination Center 1950.
Chemical-Biological Coordination Center:
Vice Chairman, Advisory Committee, 1951–52.
Member, Steering Committee, 1951–52.

International:
WHO (United Nations) Expert Advisory Panel on Drugs Liable To Produce Addiction, 1951.
Second medical mission to Japan, May-June 1951, Unitarian Service Committee and Department of the Army.
United States National Committee for International Union of Physiological Sciences 1955–59.
Chairman American team, Conference on Physiologic and Pharmacologic Basis of Anesthesiology, Japan, April-May 1956, Unitarian Service Committee and Rockefeller Foundation.

CURRICULUM VITAE OF ROBERT BLACKWELL SMITH, JR.

Born: Petersburg Virginia, November 2, 1915; son of Robert Blackwell and Mary L. (Ridout) Smith

Family: Married Esther Bergliot Ostrem of Madison, Wis., September 6, 1942. Children: Peter Blackwell, October 30, 1943; Susan Kristin, December 9, 1946; Nan Carolyn, October 15, 1948.

Religious affiliation: River Road Baptist Church, Richmond.

Clubs: Rotary, Torch, and Downtown of Richmond.

Education:
Public schools of Petersburg.
Bachelor of Science, Medical College of Virginia, school of pharmacy, 1937.
Masters of Science, University of Florida, 1938 (pharmacology and bacteriology).
Doctor of Philosophy, University of Chicago, 1941 (pharmacology and physiology).
Dr. Smith was a graduate scholar in pharmacology while at the University of Florida, and a university fellow in pharmacology at the University of Chicago.

Professional career:
1941–45: Pharmacologist, Division of Pharmacy, United States Food and Drug Administration, Washington.
1945: Made acting Chief of the Division of Pharmacology.
1945: December: Returned to the Medical College of Virginia as assistant dean of school of pharmacy.
1947: Made dean of the school of pharmacy. Continuing his activities in teaching and research, he advanced through the ranks to a full professorship of pharmacology in the schools of medicine and pharmacy.
1954: July 1: Appointed assistant president of the Medical College of Virginia.
1956: July 1: Made president of the Medical College of Virginia.

Membership in professional and scientific organizations:
American Association for the Advancement of Science.
American Pharmaceutical Association.
American Society for Pharmacology and Experimental Therapeutics.
Association of American Medical Colleges.
Richmond Academy of Medicine.
Richmond Dental Society.
Virginia Pharmaceutical Association.
Offices held in professional and scientific organizations:
Treasurer, Medical College of Virginia Foundation.
Secretary, Richmond Area University Center.
Treasurer, Virginia Council on Health and Medical Care.
Board member of:
Arthritis and Rheumatism Foundation.
Medical College of Virginia Foundation.
Richmond Area University Center.
Richmond Chamber of Commerce.
Virginia Council on Health and Medical Care.
Virginia Heart Association.
Virginia Society for Crippled Children and Adults.
Member of Committee on Food Protection of the National Research Council, and chairman of its Sub-Committee on Toxicology.
Consultant in pharmacology to the Surgeon General, United States Air Force.
Honorary societies: Sigma Xi, Phi Kappa Phi, Rho Chi.
Home address: 5409 Ditchley Road, Richmond, Va.
Business address: Medical College of Virginia, MCV Station, Richmond, Va.
Political Affiliation: Democrat.

CURRICULUM VITAE OF HENRY F. SMYTH, JR.

Education:
Bachelor of science in chemical engineering, University of Pennsylvania, 1925. Doctor of Philosophy (medical sciences), University of Pennsylvania, 1934.
Positions:
Special investigator, Department of Labor and Industries, State of Pennsylvania, July 1925 to June 1926. Study of health hazards and environmental conditions of the spray-painting operation.
Special investigator, National Safety Council, July 1926 to June 1927. Study of health hazards and environmental conditions of spray painting in auto body manufacture.
Private consultant in partnership with Henry Field Smyth, M. D., Dr. P. H., July 1927 to August 1937. Experiment and research chiefly in the field of toxicity of industrial materials.
Concurrent with the above, instructor in sanitary chemistry, department of hygiene, School of Medicine, University of Pennsylvania, September 1928 to August 1937.
Fellow (later senior fellow, now administrative fellow), chemical hygiene fellowship, Mellon Institute of Industrial Research, Pittsburgh, Pa., 1937 to date. In charge of toxicological studies sponsored by Union Carbide Corp.
Professional memberships:
Fellow: American Public Health Association.
American Institute of Chemists.
Member: American Chemical Society.
American Industrial Hygiene Association (past president).
American Institute of Food Technologists.
National Society of Professional Engineers.
Publications: Approximately 70 articles in the scientific literature reporting the toxicology of industrial materials, and methods for the study of toxicology.
Special qualifications:
Since 1931 a variable but increasing portion of my research has been devoted to studying the toxicology of materials which may enter food as either intentional or incidental additives, and to forming judgements on the safety or hazards of the use of these materials. Since 1937 I have been in charge of experimental toxicological studies for Union Carbide Corp. For 20 years I have been re-

sponsible for advising that corporation and its divisions whether or not particular chemicals may be used in particular ways without injury to health. An increasing portion of that advice refers to food additives. Since 1951 I have been a member of the toxicology subcommittee, Food Protection Committee, National Academy of Science-National Research Council.

STATEMENT OF DR. WILLIAM J. DARBY, HEAD, DEPARTMENT OF BIOCHEMISTRY, AND DIRECTOR, DIVISION OF NUTRITION, VANDERBILT UNIVERSITY SCHOOL OF MEDICINE

Dr. DARBY. Thank you, Mr. Williams.

I am certain that I speak for the panel when I say that we welcome this opportunity to appear before your subcommittee, and the members of the committee and discuss with you the considerations involved in chemical additives.

In your letter to President Bronk, dated June 26, 1957, you expressed your intention in these hearings of having scientific problems which underlie legislation discussed separate and apart from the governmental and legal aspects.

You requested the assistance of President Bronk in suggesting this panel for the purpose of discussing before the subcommittee, the scientific problems involved in testing and evaluating the safety of food additives. It is to this aspect of the problem of food additives that we should like to address ourselves.

In order to consider the subject matter we have felt that it might be desirable to divide the areas into essentially three divisions.

First, a brief discussion of the use of chemical additives in order that we can identify the nature of the problem before us.

And then, the question of evaluation of safety by the consideration of usual toxicological procedures.

And finally, the evaluation of safety in relation to possible carcinogenicity. And at this point, I would like if I might, to introduce the individual members of the panel who will participate in this discussion.

I shall start on the right. Dr. Maurice H. Seevers, chairman of the department of pharmacology, University of Michigan, Ann Arbor, Mich.; Dr. Howard C. Spencer, biochemical research department, The Dow Chemical Co., Midland, Mich.; Dr. Henry F. Smyth, Jr., Mellon Institute, Pittsburgh, Pa.; Dr. Emil M. Mrak, chairman, department of food technology, University of California, agricultural experimental station, Davis, Calif.; Dr. William B. Deichmann, chairman, department of pharmacology, University of Miami School of Medicine, Coral Gables, Fla.; Dr. R. Blackwell Smith, president, Medical College of Virginia, Richmond, Va.; Dr. F. N. Peters, vice president, research laboratories, The Quaker Oats Co., Barrington, Ill.; Mr. Harvey K. Murer, manager, research center, General Food Corp., Tarrytown, N. Y.; Dr. John H. Foulger, director of medical research, E. I. du Pont de Nemours & Co., Wilmington, Del.; Dr. Herbert E. Carter, department of chemistry and chemical engineering, University of Illinois, Urbana, Ill.; Dr. Paul R. Cannon, chairman, department of pathology, University of Chicago, Chicago, Ill.; Dr. Emerson Day, chief, division of preventive medicine, Sloan-Kettering Institute for Cancer Research, New York, N. Y.; Dr. Morton L. Levin, director, Commission on Chronic Illness, State Department of Health, Albany, N. Y.; Dr. W. C. Hueper, Na-

tional Cancer Institute, National Institutes of Health, Bethesda, Md.

As you can see, this panel represents a variety of institutions and a variety of persons with a wide background and experience in the field of chemical additives.

We thought it might be helpful if we had initially by the three members of the panel who are primarily interested in food technology a brief discussion of the use of chemical additives, to provide a setting of the problem, to give us the answers to such questions as to what additives are, where and why they may be used in foods.

And to initiate this discussion, if I might, I should like to call on Dr. Mrak.

STATEMENT OF DR. EMIL M. MRAK, CHAIRMAN, DEPARTMENT OF FOOD TECHNOLOGY, UNIVERSITY OF CALIFORNIA AGRICULTURAL EXPERIMENT STATION, DAVIS, CALIF.

Dr. MRAK. Mr. Chairman and Dr. Darby, my education consists of the bachelor of science and master of science degrees in food technology and doctor of philosophy in mycology, all from the University of California at Berkeley. I am professor of food technology and good technologist in the agricultural experiment station and chairman of the department of food technology on the Davis and Berkeley campuses of the University of California. I am also president of the Institute of Food Technologists and a member of the Food Protection Committee and Advisory Committees to the Army, Office of Naval Research, and the National Institutes of Health. We of the department of food technology at the University of California have been interested in the use of chemicals, and the possible new uses for chemicals for some time. We believe the use of chemical additives offers great possibilities in the future.

I might say in connection with the brief statement I am to make it is my understanding that pesticides are not to be considered at this time, particularly as applied to the growing and handling of crops.

If we look back at the food picture as it was 50 years ago, we will find a rather primitive situation. There was a great deal of malnutrition. We did not have a variety of foods. We did not have good foods. We had overproduction in some areas, and being from California, I am well aware of surpluses in the history of this State.

This has changed; it has changed greatly, in part due to great advances in processing and transportation and to some extent to the use of chemicals. The use of chemicals, I believe, played a very important role. I also believe that the future will see even greater developments. I will mention these very briefly.

First of all, what are the factors that influence the consumer?

First of all, factors that influence acceptability. These may be categorized under the headings: "Flavor," "Color," and "Texture."

Now I have heard a number of people state, "Why worry about color?" We have done a great deal of work on color, involving the use of taste panels, and we find that the acceptance of a commodity invariably goes up as the color is improved. We have observed that when two solutions containing the same amount of flavor are presented to a taste panel the more favorably colored sample will be preferred.

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I need not say anymore about flavor or texture.

Stability is a very important problem to the consumer as well as to the processor. There is a great deal of room for improvement in this area and here I believe chemicals can play a very important role. When we pack a food and put it into channels of distribution, deteriorative changes can take place. In the past when we spoke of spoilage we usually thought only of microbial spoilage but there are other types of spoilage that are more subtle. The foods can go downhill chemically. They can lose their nutritive value, flavor and color, and change in texture.

I believe that it is desirable to prevent these changes so in the future we will have better foods and better nutrition. We are actually working in these areas. We want to protect the foods against insects during the processing and distribution of cereals, dried fruits, and so forth.

Another factor of importance to the consumer is convenience. The processor today has taken a great deal of labor and drudgery out of the preparation of foods. The housewife has been liberated from a tremendous amount of work. Anyone today should be able to make a sponge cake. This was not true 10 years ago. Today we have prepared mixes. It is needless to say that certain chemicals are important in the preparation of convenient foods.

The consumer is also interested in other factors of acceptance. The housewife and consumer want to know their food is not only safe but is aesthetically acceptable. Chemicals may be used in cleaning and repelling insects or rodents that come into the esthetic picture.

The food must be safe. More will be said about this later. And finally, but certainly not the least, they must be high in nutritive value. We would like very much to retain the goodness in the food at the time of processing and after distribution. The ideal will be processed foods equal to the freshly harvested product.

Now I have a table that shows some of the functions of food additives.

FUNCTIONS OF CHEMICALS USED IN FOODS

I. Preservatives:
   (*a*) Microbiological spoilage.
   (*b*) Chemical deterioration.
   (*c*) Chemicals to control insects and rodents.
II. Nutrional supplements:
   (*a*) Vitamin.
   (*b*) Amino acids.
   (*c*) Minerals.
   (*d*) Calories.
III. Color modifiers:
   (*a*) Natural coloring matter.
   (*b*) Certified food dyes.
   (*c*) Derived color.
IV. Flavoring agents:
   (*a*) Synthetic.
   (*b*) Natural.
   (*c*) Flavor enhancers or extenders.
V. Chemicals which affect functional properties of foods:
   (*a*) Control of colloidal properties:
      1. Gel.
      2. Emulsion.
      3. Foam.
      4. Suspensoid.
   (*b*) Firming agents.
   (*c*) Maturing agents.

VI. Chemicals used to process foods:
(*a*) For sanitation, public health, or esthetic purpose.
(*b*) To facilitate the removal of unwanted covering (skins, hides, feathers, hair, etc.).
(*c*) Antifoam.
(*d*) Chelating agents.
(*e*) Yeast food.
VII. Chemicals to control moisture:
(*a*) Waxes.
(*b*) Anticaking agents.
VIII. Chemical used to control pH:
(*a*) Acids.
(*b*) Bases.
(*c*) Salts.
IX. Chemicals used to control physiological functions in relation to quality:
(*a*) Ripening agents.
X. Miscellaneous:
(*a*) Gases—pressure dispensing.

Finally, there is an FAO/WHO statement which I should like to include in the record.

This includes statements that I believe are very pertinent. Few are of particular importance: (1) Chemicals are added to maintain nutritive value; (2) to improve the keeping qualities; (3) to make the food more attractive to the consumer. Under this we could put the convenience factor; (4) that chemicals may be essential aids to the processor by reducing cost of production. The chemicals must be safe, and they must not be added for the point of deception.

Dr. DARBY. I think we might give copies of this Joint FAO/WHO Expert Committee Report, if the committee would like, for the record.

Mr. WILLIAMS. The committee will be glad to accept that for the record.

(The booklet referred to is as follows:)

GENERAL PRINCIPLES GOVERNING THE USE OF FOOD ADDITIVES

Report of the Joint FAO/WHO Expert Committee on Food Additives, First Session, Rome, Italy, December 3–10, 1956. Sponsored jointly by FAO and WHO

INTRODUCTION

In 1954, the Joint FAO/WHO Expert Committee on Nutrition, at its Fourth Session,[1] briefly reviewed the problem of food additives and proposed that a special conference concerned with the problem should be convened by WHO and FAO. It further suggested that this conference should consider, as a step toward international agreement and action in this field, the desirability of convening an expert committee to lay down acceptable broad general principles governing the use of food additives.

In accordance with this proposal, a joint FAO/WHO Conference on Food Additives took place in September 1955.[2] This Conference was an exploratory one and gave special attention to the contribution which FAO and WHO could make in this field along lines suggested by the Joint FAO/WHO Expert Committee on Nutrition. Following the interpretation of the term "food additives" adopted by the Joint Expert Committee, the Conference confined its discussions to "nonnutritive substances which are added intentionally to food."

The Conference further recommended that an expert committee concerned with the technical and administrative aspects of the problem should be con-

[1] Joint FAO/WHO Expert Committee on Nutrition, Fourth Report (*FAO Nutrition Meetings Report Series No. 9*) (*Wld Hlth Org. techn. Rep. Ser.* 1955, 97).
[2] Joint FAO/WHO Conference on Food Additives, Geneva, 19–22 September 1955, Report (*FAO Nutrition Meetings Report Series No. 11*) (*Wld Hlth Org. techn. Rep. Cer.* 1956, 107).

vened as soon as feasible to formulate general principles. The present Committee is the result of this recommendation.[1]

LIST OF PARTICIPANTS

Members:

Dr. E. Abramson, Professor of Food Hygiene, National Institute of Public Health, Tomteboda, Sweden
Dr. William J. Darby, Professor of Biochemistry and Director of the Division of Nutrition, Vanderbilt University, School of Medicine, Nashville, Tenn., USA (*Chairman*)
Dr. M. J. L. Dols, Cabinet Adviser in General Service to the Ministry of Agriculture, Fisheries and Food, The Hague, Netherlands
Dr. Druckrey, Professor of Pharmacology and Toxicology, Laboratories of the Surgical Clinic, University of Freiburg, Germany
Dr. B. Mukerji, Director, Central Drug Research Institute, Government of India, Lucknow, India (*Vice Chairman*)
Professor R. Truhaut, Professor de toxicologie, Faculté de pharmacie de l'université de Paris, France
Dr. J. R. Vickery, Chief, Division of Food Preservation, C. S. I. R. O., Homebush, N. S. W., Australia
Dr. Norman C. Wright, Chief Scientific Adviser (Food), Ministry of Agriculture, Fisheries and Food, London, England

Observers (invited by FAO):

M. H. F. Dupont, Secrétaire général, Paris
International Commission for Agricultural Industries (CIIA)
Sir Charles Dodds, Past President, Section of Biological Chemistry and Vice President, London
International Union for Pure and Applied Chemistry (IUPAC)
Professor A. Buffa, Stazione Agraria Sperimentale, Parma
Permanent International Committee on Canned Foods (CIPC)

Secretariat:

Dr. A. G. van Veen, Chief, Food Processing and Preparation Branch, Nutrition Division, FAO (*Joint Secretary*)
Dr. R. A. Chapman, Scientist (Food Additives), Section of Health Laboratory Methods, WHO (*Joint Secretary*)
Mr. M. Kondrup, Food Technologist, Nutrition Division, FAO
Mr. F. H. Townshend, Legal Research Officer, Legislative Service, Information Division, FAO
Dr. Elba Chiaserotti-Gasser, Consultant, Nutrition Division, FAO

ORGANIZATION OF THE COMMITTEE

The Committee was attended by eight members and also by observers from the International Union of Pure and Applied Chemistry, the International Committee of Agricultural Industries, and the Permanent International Commission on Canned Foods. It was opened by the Director-General of FAO, Mr. B. R. Sen, on behalf of both FAO and WHO. Dr. William J. Darby and Dr. B. Mukerji were elected Chairman and Vice-Chairman respectively of the Committee. Members of the staff of FAO and WHO acted as technical secretaries.

TERMS OF REFERENCE

The Committee was requested to formulate general principles governing the use of food additives. It restricted its discussions to "nonnutritive substances added intentionally to food, generally in small quantities, to improve its appearance, flavor, texture or storage properties," as proposed by the Joint FAO/WHO Conference on Food Additives in 1955. Substances which are added primarily for

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[1] The WHO Executive Board, at its nineteenth session, adopted the following resolution:
The Executive Board:
1. *Notes* the first report of the Joint FAO/WHO Expert Committee on Food Additives;
2. *Thanks* the members of the Committee for their work;
3. *Expresses* its appreciation to the Food and Agriculture Organization for its collaboration; and
4. *Authorizes* publication of the report.
(Resolution EB19.R16, *Off. Rec Wld Hlth Org.*, 1957, 76,5).

their nutritive value, such as vitamins and minerals, were not considered, though it was recognized that in certain instances chemicals added to food to impart a desired quality or for some other functional purpose may also be of nutritional value.

CIRCUMSTANCES GOVERNING THE USE OF FOOD ADDITIVES

The increase in the number of chemicals used or proposed for use in or on foods has imposed upon public-health authorities and other governmental agencies the responsibility for deciding whether or not such substances should be employed. The socioeconomic position of a country is an important factor in arriving at such decisions. Additives can contribute greatly to the preservation of food; for example, they can help prevent the wastage of seasonal surpluses. In economically underdeveloped countries, lack of modern storage facilities and the inadequacy of transport and communications may increase the necessity of using certain food additives for purposes of food preservation. Again, in tropical regions, where high temperature or humidity favor microbial attack and increase the rate of development of oxidative rancidity, a wider use of antimicrobial agents and antioxidants may be justified than in more temperate climates. In these regions possible risks associated with the increased use of food additives must be weighed against the benefits in the form of preventing wastage and making more food available in areas in which it is needed. In these circumstances, however, food additives should be used to supplement the effectiveness of traditional methods of food preservation rather than to replace these methods.

In countries which are technically and economically highly developed, the availability of adequate facilities for refrigerated transport and storage reduces, even if it does not eliminate, the need for antimicrobial agents. In these countries, however, there is an increasing demand for more attractive foods, for uniformity of quality and for a wide choice at all seasons of the year. Moreover, large quantities of many of the foods consumed have to be transported from distant producing areas, a fact which may create special transport and storage problems. For such purposes the variety of useful food additives is great and their employment promotes the better utilization of the available foods.

The extent to which food additives are likely to be needed and their nature will therefore vary considerably from region to region and even from country to country. In decisions concerning the use of an additive, attention should be given to its technological usefulness, protection of the consumer against deception, the use of inferior techniques in processing and, above all, to the evidence bearing on the safety for use of the substance. These points are discussed in the following sections in this order.

A. Technical Purposes for which Food Additives are Used

There are a number of circumstances in which there is technological justification for the use of acceptable food additives to the advantage of the consumer.

(*i*) *Maintenance of the nutritional quality of a food.*—It is desirable in all circumstances to maintain the nutritional quality of foods, but this is of special importance in countries in which the supply of essential nutrients in the usual diet is marginal or deficient. Any losses may then become serious and it is particularly necessary to avoid losses of the less-stable vitamins. A typical example of the use of an additive in checking such losses is the addition of an antioxidant to edible fats which contain substantial amounts of *beta*-carotene or vitamin A, destruction of which may be accelerated by the onset of rancidity during storage. In certain circumstances the nutritional value of a food may incidentally be enhanced by the use of additives. Thus, ascorbic acid, when employed as an antioxidant will increase the antiscorbutic value of foods, such as fruit products, to which it it added, while the coloring of margarine with *beta*-carotene will enhance its vitamin A activity.

(*ii*) *Enhancement of keeping quality or stability, with resulting reduction in food wastage.*—Advantage should be taken of the many achievements of chemists and food technologists in making available a wide range of acceptable additives which can materially reduce loss of food. These food additives include a great number of agents which retard the onset of deterioration. Among these are the antioxitants, various types of antimicrobial agents, inert gases, curing agents for meats, and many spices.

(*iii*) *Making foods attractive to the consumer.*—Nonnutritive additives used to increase the appeal of a food to the consumer are, chiefly, colors, flavoring agents, emulsifying, stabilizing and thickening agents, bleaching agents, and

clarifiers. The value of color in food products lies mainly in the fact that the interest of consumers in a food may decrease if it does not have the color to which they have become accustomed. Typical instances are manufactured dairy products, such as butter and cheese, the natural color of which may vary from season to season, canned and pulped fruits and vegetables, which have lost some of their original color during the processing necessary for their preservation, sugar confectionery and beverages. Flavoring agents are likewise useful in increasing acceptability. In some countries emulsifying and stabilizing agents are used to improve the texture of bakery products, to impart smoothness to ice cream, and to give uniform consistency to processed fats such as shortening and margarine. In many cases the product would not be widely acceptable unless such agents are used in manufacture. The desire that certain foods should be without color, and the preference for a certain consistency in a food or beverage, for a clear beverage, or for other special properties in their foods, has led to the use of other additives such as bleaching agents, thickeners, and clarifiers.

Certain plant, fish, and animal products formerly used largely as animal food are being increasingly used as human food. In several instances this has been made possible through the application of food additives such as flavors, colors, and agents which improve texture.

Attention must be drawn to the fact that processing practices made possible by the use of additives which increase the appeal of food to consumers should not lead to their deception. Adequate labelling of food products will help to prevent such deception (p. 17).

(*iv*) *Providing essential aids in food processing.*—Some modern manufacturing processes require the use of stabilizing, clarifying, oxidizing and sequestering agents, acids, alkalis, buffer salts, and other processing materials. Many of these substances are used seasonally and by only a segment of a given food industry. Their use, however, often permits the economical large-scale manufacture of foods of constant composition and quality throughout the year.

B. Situations in which Food Additives should not be Used

Apart from questions of acute and chronic toxicity which will be dealt with later, there are a number of situations in which the use of certain food additives is not in the best interest of the consumer and, therefore, should not be permitted.

(*i*) *To disguise the use of faulty processing and handling techniques.*—In some classes of foods the use of food additives may lead to abuses which are difficult to detect and thus encourage faulty or careless processing methods, such as lack of proper hygienic precautions.

(*ii*) *To deceive the consumer.*—The use of an additive should not lead the consumer to believe that he is purchasing food of quality higher than it really is. Typical examples include the use of strong flavoring substances to disguise incipient putrefaction, or the use of artificial colors to disguise stale or inferior raw materials. However, the use of additives in foods of high quality, the appearance, texture, and attractiveness of which have been adversely affected by the use of good manufacturing processes, may be justified. There is a greater risk of deception in the use of food additives with foods sold in the raw state than with processed foods. In the case of the former, labeling is largely impracticable, and distributors may be tempted to use additives to give inferior products the appearance of more expensive varieties. Moreover, the consumer does not usually expect that raw foods will contain intentional additives.

(*iii*) *When the result is a substantial reduction of the nutritive value of the food.*—The use of certain additives may result in the destruction of nutrients. Thus, an additive which possesses oxidizing properties may cause a reduction in the content of a labile vitamin. Again, a nutrient thickening agent such as sugar or gelatine, normally used in substantial quantities, may be replaced by a nonnutrient agent. While in some instances there may be no objection to this practice, in others the resulting decrease in nutrient content may be significant.

It is desirable to restrict as far as possible the use of nonnutritive substances to replace ingredients which have nutritive value. This is of special importance with general purpose foods. However, the use of certain nonnutritive additives is justified in making possible the preparation of foods designed for medical or other special purposes.

(*iv*) *When the desired effect can be obtained by good manufacturing practices which are economically feasible.*—New and improved processing procedures can often eliminate the need for an additive. For example, in some situations color may be retained in a processed food by improvement in processing conditions or

the need for a preservative may be eliminated by refrigeration or other means during storage or transport. Where feasible, these improvements are to be preferred to the use of an additive. Attention should be drawn to the possibility of certain antimicrobial agents losing their effectiveness by the production of resistant strains of food spoilage organisms after a period of use.

C. Safety for Use of Food Additives

Safety for use is an all-important consideration. While it is impossible to establish absolute proof of the nontoxicity of a specified use of an additive for all human beings under all conditions, critically designed animal tests of the physiological, pharmacological, and biochemical behavior of a proposed additive can provide a reasonable basis for evaluating the safety of use of a food additive at a specified level of intake. The Committee was informed that a further technical committee would be convened to deal specifically with such toxicological procedures. For this reason, no attempt has been made in this report to deal with the problem of toxicity in detail.

The Committee stresses the principle, however, that any decision to use an intentional additive must be based on the considered judgment of properly qualified scientists that the intake of the additive will be substantially below any level which could be harmful to consumers. The decision as to a safe level should be based on knowledge of the maximum dietary level that produces no unfavorable response in test animals, of the severity and type of response in animals above that level, and of the estimated potential intake of the additive.

Toxicological considerations should include not only the food additive as such, but also substances produced in the food by the action of the additive and the possibility of the formation of toxic substances from the additive during processing, storage, and household preparation. The possible interaction of additives should also be borne in mind.

Judgment as to safety must recognize that there may be groups within a population which, because of physiological state or organic disease, may be specially sensitive to the additive concerned. These groups include those suffering from a variety of chronic diseases, for example, malnutrition, parasitosis and certain degeneraitve conditions. In this connection, it must be emphasized that while easily identifiable foods are readily avoided, this is not so with some food additives.

It is therefore clear that the study and laboratory testing of a substance, and the scientific advice given concerning its use, may well differ from country to country.

Permitted additives should be subjected to continuing observation for possible deleterious effects under changing conditions of use. They should be reappraised whenever indicated by advances in knowledge. Special recognition in such reappraisals should be given to improvements in toxicological methodology. In some countries additives are employed without the safeguard provided by appropriate study. The limited facilities for toxicological work in many countries should be expanded in order to meet the needs for these investigations. They should likewise be a continuing increase in the international cooperation and exchange of information in this area.

OTHER FACTORS TO BE TAKEN INTO ACCOUNT IN FOOD ADDITIVES CONTROL

A. Bearing of the Usefulness on the Decision to Permit a Food Additive

When a new food additive is proposed for use, clear evidence must be available to show that benefits to the consumer will ensue. In comparison with additives already in use, it should either be equal or more effective in producing an acceptable product, or should confer on that product acceptable qualities not produced by other additives, or should be cheaper and thus tend to reduce the price of the food to the consumer. The potential health hazard should be no greater and preferably lower than that of comparable approved additives.

B. Classes of Food in which the Use of Food Additives should be Limited

In principle, the use of intentional additives should be limited in those classes of foods which constitute a considerable proportion of the diet, and particular care should be exercised in granting permission for such use. Since the greater portion of the diet of infants and young children may be derived from a few foods, the limitation of additives in these foods is especially to be desired.

C. Need of Specifications of Identity of Food Additives

The presence of harmful impurities in food additives can be excluded most effectively by the establishment of specifications of purity. Food legislation should make provision for limits in foods of inorganic impurities such as arsenic and heavy metals. These requirements not only provide protection from the harmful effects of such contaminants, but also have a beneficial effect on the general level of food processing. On the other hand, some food additives may contain organic impurities which are particularly dangerous, the detection of which is difficult or impossible after admixture with food. In such instances it is most important that the specifications for the food additives should exclude or limit these substances.

It is necessary that food additives, many of which are not single chemical substances, should be identifiable in chemical and physical terms. The components of such mixtures should be described and the limits of reproducible composition defined. Such identification is essential in order to compare the results of toxicity testing and to ensure that the additive tested is the additive which is used in practice.

D. Limitation on Levels of Use

The amount of an authorized additive used in food should be the minimum necessary to produce the desired effect. Some additives are self-limiting in the amounts which may be employed, due to the quantities which are technologically useful. With others, the concentrations which are likely to be used will be strictly limited by economic considerations.

However, it may be necessary to set an upper limit on the amount of some additives to be used, either in foods in general or in specific groups of foods. Such limits should be determined primarily with regard to safety, but technological considerations designed to prevent deception or the use of faulty processing techniques should also be given attention. They should be established with due attention to:

(*a*) the estimated level of consumption of the food or foods for which the additive is proposed;

(*b*) minimal levels which in animal studies produce significant deviations from normal physiological behavior;

(*c*) an adequate margin of safety to reduce to a minimum any hazard to health in all groups of consumers.

E. Possible Combined Effect of Food Additives

In fixing such limits as may be necessary in regard to the levels of additives to be permitted in foods or in individual groups of foods, care should be taken to avoid a gradual and unrecognized increase in the amounts present in the total diet to a point at which an adequate margain of safety is no longer ensured. At times it may be that safeguards against the indiscriminate use of an additive should be established by limiting its use to specific foods or groups.

In addition, attention should be given to the question of whether the combined effects of a number of additives with similar toxicological properties might produce an undesirable summation of reactions. Finally, there may be substances which, because of some special biological property, may have the effect of making other additives harmful. Evidence bearing on these points deserves consideration in decisions pertaining to the use of additives.

F. Need for Legal Authorization

Experience has indicated that it is essential to maintain legal control over the use of food additives. They should be used only after authorization by the appropriate governmental body.

G. Relative Merits of Using Permitted and Prohibited Lists

The Committee considered that the legal control of food additives should be based on the principle of a permitted list. This system effectively prevents the addition of any new substances to food until an adequate basis for judgment of their freedom from health hazard has been established. The safeguarding of the public health is impossible if manufacturers are allowed to use new substances before appropriate study has established their suitability for such use. The alternative method of a prohibited list may entail a considerable risk to the community since it can allow a harmful additive to be used for several years before the accumulation of sufficient evidence to warrant placing it on the prohibited list.

The use of a permitted list eliminates such dangers. At the same time it places all those wishing to introduce an additive in the same position inasmuch as adequate toxicological data must be presented before a substance can be used. The permitted list thereby tends to place the responsibility for such investigations on those who wish to employ the additive for food. It also has the added advantage of reducing the number of substances requiring extensive investigation by regulatory agencies.

The principle of permitting only certain substances has been criticized on the basis that it tends to create vested interests. Provision must therefore be made for the admission with a minimum of delay of properly tested food additives which are considered desirable. Similarly there should be provision for the immediate withdrawal of substances from use should such action become necessary for protection of health or other reasons. The legal procedure adopted for the control of food additives should not have the effect of discouraging inventiveness through impeding progress in the improvement of food processing.

While the number of food additives required for a particular purpose should be kept as small as possible, it would not be practicable for the responsible authorities to limit any group to a specific number, i. e., to insist that the inclusion in the list of a new additive requires the eliminaton of one already permitted.

II. Desirability and Nature of Declaration

The Committee agreed that in principle consumers should be informed of the presence of additives in their food. Label declaration is the most effective method of achieving this result, but in some countries alternative approaches have been adopted. Thus, in the United States, standards of identity for foods have been established which are available to the public and which list the permissive ingredients. These standards require the label declaration of only certain specified classes of additives. Provided that strict legal control over the use of additives is exercised, label declaration is necessary to inform the consumer rather than for the protection of his health.

Exceptions may have to be made for certain classes of food. For example, some foods are normally sold in an unpackaged form and in such circumstances label declaration becomes impractical. In other instances, the addition of certain additives is sufficiently evident and therefore label declaration may not be necessary.

Since most consumers are uniformed as to the nature and purposes of additives, confusion and suspicion tend to be created in their minds if the manufacturer is compelled by law to state the chemical name and concentration of the additive which is used. Therefore, simple declarations of the presence of a particular class of additives such as "artificial color added" or "artificial flavor added" are sufficient.

When nonnutritive additives are deliberately employed to replace nutrients in the preparation of foods for special uses, it is clearly necessary to identify the use for which the food is intended in order to avoid deception of the consumer.

I. Regulatory Control

As in other aspects of food legislation, it is virtually useless to issue regulations governing the control of additives unless the law can be enforced. Enforcement requires the employment of trained food inspectors supported by adequately staffed and equipped food control laboratories.

It is desirable to have reliable analytical methods for the detection and, if necessary, the estimation of food additives, authorized as well as nonpermitted, in each class of food. There are, however, difficulties in the development of analytical procedures for the determination of substances in certain groups, for example, flavoring agents. The concentration of some of these additives is self-limiting. However, when it is necessary to establish an upper limit of concentration within a food, a reliable quantitative method should be available before the substance is authorized for use.

In communities where only limited regulatory control can be exercised, it seems desirable that permission should be confined to a small number of additives possessing especially wide margins of safety.

RECOMMENDATIONS TO FAO AND WHO

The Committee reviewed and approved the joint FAO/WHO program on food additives, including *inter alia* the publication *Current Food Additive Legislation* and the compilation of data sheets on food colors. It recommends that FAO and WHO should:

(1) continue and expand their activities in this field, including the compilation and publication of food additive legislation and the dissemination of physical, chemical and toxicological data on individual food additives;

(2) extend the publication program of food additive legislation to include summary reviews of relevant legislation in individual countries;

(3) convene as soon as practicable a second session of the Joint FAO/WHO Expert Committee on Food Additives to consider procedures for the toxicological testing of food additives;

(4) arrange by appropriate means for a comprehensive review of analytical procedures and standards of purity and, if necessary, convene a further session of the Joint Committee to review progress in this field;

(5) continue to consult, in their work on food additives, governmental and nongovernmental organizations and groups which are active in this field.

SUMMARY

(1) The increase in the number of chemicals used or proposed for use in or on foods has imposed upon public health authorities and other governmental agencies the responsibility for deciding whether or not such substances should be employed. Food additives have a legitimate use in the food processing and distribution systems of both technologically advanced and of less well developed countries, in that they promote the better utilization of available foods.

(2) The use of food additives to the advantage of the consumer may be technologically justified when it serves the following purposes:

(*a*) The maintenance of the nutritional quality of a food;

(*b*) the enhancement of keeping quality or stability with resulting reduction in food wastage;

(*c*) making foods attractive to the consumer in a manner which does not lead to deception;

(*d*) providing essential aids in food processing.

(3) The use of food additives is not in the best interest of the consumer in the following situations and should not be permitted:

(*a*) to disguise the use of faulty processing and handling techniques;

(*b*) to deceive the consumer;

(*c*) when the result is a substantial reduction of the nutritive value of the food;

(*d*) when the desired effect can be obtained by good manufacturing practices which are economically feasible.

(4) Safety for use of an additive is an all-important consideration. While it is impossible to establish absolute proof of the nontoxicity of a specified use of an additive for all human beings under all conditions, critically designed animal tests of the physiological, pharmacological and biochemical behavior of a proposed additive can provide a reasonable basis for evaluating the safety of use of a food additive at a specified level of intake. Any decision to use an intentional additive must be based on the considered judgment of properly qualified scientists that the intake of the additive will be substantially below any level which could be harmful to consumers. Permitted additives should be subjected to continuing observation for possible deleterious effects under changing conditions of use. They should be reappraised whenever indicated by advance in knowledge. Special recognition in such reappraisals should be given to improvements in toxicological methodology.

(5) Other factors must be taken into account in food additives control. When a new food additive is proposed for use, clear evidence must be available to show that benefits to the consumer will ensue. In classes of foods which constitute a considerable proportion of the diet the use of intentional additives should, in principle, be limited. The presence of harmful impurities in food additives can be excluded most effectively by the establishment of specifications of purity. Food additives should be identifiable in chemical and physical terms.

(6) The amount of an authorized additive used in food should be the minimum necessary to produce the desired effect. The limit should be established with due attention to:

(*a*) the estimated level of consumption of the food or foods for which the additive is proposed;

(*b*) minimal levels which in animal studies produce significant deviations from normal physiological behavior;

(*c*) an adequate margin of safety to reduce to a minimum any hazard to health in all groups of consumers.

(7) Legal control over the use of food additives is essential. This is best accomplished through the use of a permitted list, which effectively prevents the addition of any new substances to food until an adequate basis for judgment of their freedom from health hazard has been established. The alternative method of a prohibited list involves risk, since it may result in the use of a harmful additive before it has been adequately studied.

(8) In principle, consumers should be informed of the presence of additives in their food. Label declaration is the most effective method of achieving this result. A simple declaration of the presence of a particular class of additive is sufficient.

(9) Regulations governing the control of food additives are useless unless the law can be enforced. This requires trained food inspectors, food control laboratories, and reliable analytical methods.

Mr. WILLIAMS. Should we proceed with the questions as each member of the panel testifies, or should we wait until you have had the opening statements of all of them.

Mr. DIES. Let them conclude their opening statements.

Dr. DARBY. If you would like, perhaps, we might conclude the opening statements. Shall we call on the food technologists and then perhaps open for questions?

Mr. WILLIAMS. All right, you may do so.

Dr. DARBY. If that is agreeable I shall ask Mr. Murer to comment.

STATEMENT OF HARVEY K. MURER, MANAGER, RESEARCH CENTER, GENERAL FOODS CORP., TARRYTOWN, N. Y.

Mr. MURER. Mr. Chairman and Dr. Darby, I think the main thing that I can contribute at this point would be to say that from the standpoint of food manufacturing I can heartily endorse the things that Dr. Mrak has said concerning the usefulness and the necessity for the use of chemical additives, chemical processing, and knowledge in the food field.

Mr. WILLIAMS. May I interrupt you there. I see our colleague Mr. Miller, one of the authors, is here. I would like to invite him if he would like to come to sit with the committee.

Mr. MILLER. Thank you very much.

Mr. MURER. I would like to emphasize the point I think that Dr. Mrak made about our food supply. We happen to be blessed with the most abundant and unquestionably the finest food supply of any area of the world.

It seems to me there should be no question in anyone's mind that science and technology, including the use of chemical additives, has played a very important and decisive role in the improvement of our foods.

I should like to emphasize a point with respect to the usefulness of chemical additives. The problems associated with their use are technical. Each chemical additive presents an individual problem with respect to why it is used and whether or not it performs a useful function. The usefulness, therefore, of any chemical additive has to be determined technically and must be judged on its individual merits.

We cannot make a blanket statement that this or that chemical additive will be useful for any particular purpose. Consumer acceptance demonstrates in the last analysis that this is in fact the case.

I do not think anyone is more conscious than the food industry of the fact that we have no means within our own areas to decide finally whether or not a chemical additive or a process that was used in the food business is going to be acceptable to the public.

We happen to be in the consumer-acceptance business, and consumer acceptance is determined in the market place.

We have long since learned in our industry that we cannot make consumer judgments. Certainly, the consumer is the ultimate person to decide whether or not a new food is or is not going to be successful, or whether a change in the food made by chemical additives will or will not permit us to do a better job.

We must consider chemical additives from the standpoint of the total process of manufacturing which, incidentally, is now decidedly different, and also in relation to keeping quality.

The advent of the very high concentration of urban population and the distribution problems in the food industry are situations that bring about the necessity for better keeping qualities, better processing, and better handling of foods. We simply could not supply the public if we did not have the benefit of modern technology. We must bring the foods to the public in an acceptable, convenient, and useful fashion.

I would like to emphasize another point in this regard, and that is that we cannot judge the usefulness of additives on the basis of whether or not they supply some particular nutrient or vitamin, calories, proteins, or other needed dietary additives. It is true in many instances that these may be supplied by chemical additives. If the additives bring good wholesome food to the public in a manner such that the public will use and eat the food, additives form a useful purpose.

It is one thing to sit down and decide what people should eat and to apply our knowledge to the system, but we have accomplished nothing if we do not get these goods to the public in a manner such that they will use them. Nutrition starts, in fact, after they eat the food and not in the laboratory where we decide, or try to decide, what nutrition should be.

In this connection, chemicals and processing have a very important role.

I should like to emphasize one other point. In the food industry we have no technical right to differentiate, nor is there any justification for a differentiation, between the chemicals that are naturally present in all foods that we eat, as contrasted to those chemical additives added intentionally.

These are the same problems that are connected with safety in relation to whether chemical additives are manufactured or are synthetic. Therefore, we must look at the safety and the usefulness of chemicals, not from the standpoint of additives that we may synthesize in the laboratory, but from the total food that we manufacture and process. The one problem is no different than the other.

I certainly would like to emphasize the fact that we should not in any way stifle this scientific progress which has brought, in my estima-

tion, such an excellent food supply to us. I do not, and I am certain no one else in the food industry doubts the fact that we should put safety first. I know of no one who has not. I should like to emphasize that, so far as I know, all responsible food manufacturers have for a long time been conscious of safety. In many of them there has been an ironclad company policy for years regarding the use of additives.

In our own organization we have spent tremendous research funds not only in the work of testing chemicals but also in the evaluation of the natural products that we merchandise, regardless of whether any chemical additives have been added or not. This has been standard practice for years.

We believe that this testing is an essential and absolute part of modern food technology and part of our responsibility to protect the public.

We do not believe that we can in any way standardize these procedures, either with respect to determining the usefulness of an additive or its safety. Each one presents its own particular problem, and we must approach it just as any other research problem. We in no way feel that we can shirk this responsibility whether or not it is actually binding by legislation.

I would like to emphasize that in our opinion the public interest is best served by the stimulation and encouragement of the use of scientific techniques in the food industry, in cooperation with the chemical industry and the Government services, and we should emphasize in whatever we do that safety should be the first criterion.

Dr. DARBY. Thank you. Next, may we ask Dr. Peters to speak.

STATEMENT OF DR. F. N. PETERS, VICE PRESIDENT, RESEARCH, THE QUAKER OATS CO., BARRINGTON, ILL.

Dr. PETERS. Mr. Williams, Dr. Darby. As the two previous gentlemen spoke, I checked off one by one the notes in front of me and find most of the points I had intended to discuss have been mentioned. However, may I take a little different viewpoint, not only for this committee, which has heard so much on this subject before, but for the benefit of the members of the press who are also here.

First, this business of chemicals in foods, which I shall refer to as "food additives," is not new. There have always been food additives, natural and synthetic, added deliberately and also acccidentally. I remember a long time ago, on a farm in Missouri I operated a small wooden churn, up and down, up and down, up and down. Sometimes the butter would form in 5 or 6 minutes, and again it required what seemed to be hours. Why? Simply because the chemical composition of the sour cream in the churn was not always suitable for rapid formation of butter. There was too much acid, or too little acid, or not enough of some vital ingredient. I could spend the time necessary to form butter in spite of the lack of the proper type of mixture. But the modern dairy must avoid the time-consuming delays and, hence, adds a harmless ingredient to create the proper butter-making conditions.

Nature does not always produce perfection. Thus, for generations man has improved upon nature. This has resulted in great

improvements in health. A striking example is the bread of the Mexicans, coming down from the Aztecs. This bread, tortillas, is made by steeping corn with limewater. The act of adding lime to a food might appear pernicious to the uninitiated. However, the lime furnishes vital quantities of calcium to the diet of those people consuming tortillas. Proper formation of bones and teeth is impossible without sufficient calcium and, hence, it can truthfully be said that tortillas with their lime have been a lifesaver for generations of Central Americans. In the Mexican and Central American dietary, insofar as I know, there is no adequate substitute for tortillas.

Cheese requires the addition of chemicals for its production. So does yogurt. Whether it is an acid or enzyme produced by a bacterium or produced in a factory, the end result when placed in the food we eat is the same. Thus, it is clear that chemicals, or additives, have been used in foods for centuries. When my mother couldn't get the apple jelly to jell she added a little pectin, although she had never heard of pectin—she called it rhubarb. She did know that a little rhubarb added to apple jelly made it jell better. Nature gives some apples enough pectin for jellymaking; but if nature fails, a food additive put in by human hands does the same thing.

Obviously, in modern food manufacture to which Mr. Murer referred, product uniformity is essential. One cannot stay in the jelly business if a case out of every few hundred remains liquid. If nature does not add to each apple the same amount of essential chemicals, such as pectin or malic acid, the food technologist must compensate for such failure.

Much of that which we are doing with food additives involves a leveling off or standardization of the amounts of natural chemicals that nature has furnished. There is nothing much new or mysterious about it. I have mentioned acids and the alkali, lime, that have been used for generations. There are others, such as preservatives or stabilizers and antioxidants. This latter is merely a polysyllabic word for things that prevent destruction or deterioration from exposure to air.

Years ago we stored eggs in a water-glass solution. They could be coated with water-glass—some called it sodium silicate. It preserved eggs. My mother poured wax over jelly to prevent the chemical, oxygen, from spoiling the flavor, and air from removing moisture. Today we put wax on paper and use it to cover food, or we add an antioxidant to the paper and wrap that around bacon or butter to prevent the deleterious action of oxygen.

Just as air, heat, and light will cause paint to crack or discolor, so will they cause the molecules in fat to "crack". These "cracked" molecules often are unpleasant tasting and may be deleterious to the human organism. The use of proper additives or antioxidants will delay or prevent the formation of these undesirable cracked products. The food technologist, gentlemen, is trying to discover what foods are best for our bodies, and then to produce them in a stable, uniform manner.

Now, I believe some of us are prone to believe that everything in nature is benign. There are many horrible things in nature. Who would suspect that navy beans would kill a chicken, pig, or rat. Millions of tons of soybeans are grown each year. Unless properly heat-

treated, soybean meal is very toxic for chickens. The common navy bean, raw, as the major source of protein in the ration of laboratory rats will kill them. We do not think of these as poison, but as common everyday food. But, in their natural state, they are far from harmless. Man must cause a chemical alteration within the bean or soybean before it is suitable for use as food.

As Mr. Murer said a while ago, obviously foods must be safe, and this will be discussed by others in the program. But chemical additives are necessary to even out the vagaries of nature, to compensate for its shortcomings. Additives used for this purpose are essential for large-scale uniform production. They may be added also for nutritional or public-health reasons. Additives such as vitamins and minerals are used for improvement of nutritional values and are generally approved, yet some faddists and proponents of so-called natural foods object to the use of any synthetic vitamins. A third class of additives is condiments and colors, materials used to enhance taste and eye appeal. Salt is a good example of the first category. Synthetic products predominate in the food-color field, although there are vegetable colors such as carotene and annatto. It should be remembered, however, that because a color is natural is no guaranty that it is wholesome or safe for use, and likewise, a color is not unsafe just because it is produced by chemical synthesis.

Mr. DARBY. I wonder if any members of the panel or members of the committee, would like to ask any questions or make any additional points on the aspect of the problem that has been presented thus far?

Mr. WILLIAMS. Are there any questions on the part of the members. I would like to ask one question of the panel. That is with respect to the term "functional value," which is used in some of these bills.

Would the chairman illustrate for us an additive that is in current use in foods which has no functional value?

Mr. DARBY. I will put that question to the panel.

Dr. MURER. Which has no functional value?

Mr. WILLIAMS. Yes; which has no functional value which is in current use. That term is used in some of these bills that give the Food and Drug Administration the right to determine whether the additive has a functional value and whether the additive may not be used.

I thought that the panel might be able to enlighten me.

Dr. FOULGER. Economically I think that should be a problem. The so-called food additives are expensive. They are expensive on the voluntary system of testing, and they would be equally expensive on the mandatory system of testing.

I hardly think that any food processor is going to add to the cost of his food in a market which is strongly competitive by adding to his food something that is costly and has absolutely no functional value.

Mr. WILLIAMS. I would think so, too.

Dr. FOULGER. It would not seem horse sense, if you describe horse sense as the sense that prevents horses from betting on humans.

Mr. WILLIAMS. One of these gentlemen, Dr. Mrak who testified first——

Dr. DARBY. Dr. Mrak.

Mr. WILLIAMS. Mentioned the use of additives for purposes of deception. Would you give us an example of a case of that sort.

Dr. MRAK. I can give you a case of an illegal one. The addition of sulfur dioxide to hamburger. But the person caught at it in my State and in Interstate Commerce is in trouble.

Mr. WILLIAMS. What is the purpose of that?

Dr. MRAK. Improvement of color.

Mr. WILLIAMS. Are there any other questions?

Mr. DOLLINGER. Some of the additives are cancer producing, are they not? Some have been cancer producing, have they not?

Dr. DARBY. I think that some things may be carcinogenic, cancer-producing. This is a subject which we will get into later.

Mr. DOLLINGER. I am sorry. I will wait for that, then.

Dr. DARBY. You had a comment, I believe, sir?

Dr. DEICHMANN. I should like to give an example of a chemical which serves a useful purpose before it comes in contact with food. The compound is octadecylamine. It is added to boiler water to prevent oxidation, that is the formation of rust on the inside of a boiler. Traces of octadecylamine pass with the steam from such a boiler into foods which are heated by this method in hospital, hotel, or other kitchens. In this manner, octadecylamine becomes a food additive. A similar problem would be created, if octadecylamine would be added to water suppiles to prevent oxidation of tanks and pipes. Traces of this free chemical would travel with the water to all the kitchens supplied by this system.

Mr. WILLIAMS. That is what would be considered an incidental use?

Dr. DEICHMANN. That is correct.

Dr. DARBY. Any further questions or comments from the panel?

Dr. HUEPER. How far does advertising go into the acceptability of food? How far does advertising influence the acceptability of the food by the public?

Dr. DARBY. Dr. Mrak.

Dr. MRAK. During the war, I was associated with the Office of Quartermaster General, and this may be different, but I think it applies. We were quite concerned with the rejection of rations overseas. And when I first became associated with the Office of Quartermaster General there was a philosophy that if you give a soldier anything they would eat it. But they soon learned as some of you know, a lot of the rations were discarded. And one of our British colleagues told me that some of the roads in Burma were paved with the British rations. Well, apparently, people may be hungry, they may be under stress and they just won't eat anything and everything. The food must be edible, at least, on the basis of this experience.

Dr. PETERS. I do not believe people can be persuaded in large numbers to use a food repeatedly unless its taste is good, regardless of the amount of advertising. Of course, some sales can be forced by advertising, but large-scale repeat purchases are based upon palatability, eye appeal, and consumer satisfaction.

A very good example of this is a wartime experience. The Canadian Government was loath to accept the United States standards for enriched flour, which involved the addition of synthetic vitamins. Therefore, the Government developed a Canadian approved flour similar in some respects to our own whole-wheat flour. It was dark in color, contained some bran and a considerable amount of natural vitamins, including B_1. In spite of all the efforts of the Canadian Gov-

ernment, its Ministry of Health, local health groups, appeals to patriotism, advertising posters, and whatnot—in spite of all these efforts, the consumption of this flour at the end of several years was about 6 percent of the total. People will not eat a food if they don't like it.

I would like to add this comment regarding determination of functional values of food additives. It seems obvious that a food manufacturer would never use an additive without some reason. He, at least, must believe the additive has functional value. If the purpose is to conceal inferiority or to mask the odor of decomposition the additive should not be permitted, and I believe the Food and Drug Administration has power under present law to prevent deception of this kind. But functional value per se has nothing to do with public health or safety; hence, so long as public health is not endangered and no fraud is perpetrated upon the consumer there seems no cogent reason why functional value should concern the Food and Drug Administration. The food manufacturer is the best judge of functionality. His product must be pleasing or he will have no customers. He cannot force people to eat something they do not like.

Dr. MRAK. That was our experience with the soldiers, too?

Dr. FOULGER. I think it goes further than that. Nutrition is not merely a matter of presenting to a person so many calories of carbohydrates or fats. There is an esthetic side. The texture of the food, its appearance, odor, color must be appealing to the senses. If they are not, the automatic physiological controls of the body may, after a few days, lead to the rejection of what the eater tries to take into his mouth. They may even cause him to vomit. He may, thus, get into poor physical condition, first, because of not eating, and, second, because in vomiting he may alter the balance of the internal fluids of the body.

There is something much more to the whole business of nutrition than merely a mass of food. And anybody who has been an infantryman in either war, feeding on dog biscuits and hardtack, or in the British Army First World War vegetable rations, will realize what I am talking about, not as a physician but just as man-to-man eating.

Dr. DARBY. I think it might be well to point out further that that which is appealing to one group of people, one section of the population in the United States, is not necessarily the same as that which will appeal to another. That has to do with flavor, with color, with texture, with method of preparation generally. And you find this rather strikingly in areas where people, as someone said here a moment ago, may actually be hungry but because of a difference in the appearance or difference in the taste or texture of food, may not eat sufficient of their food to meet their needs.

I think that there is no question that the advertising of food, if I understood you correctly, sir——

Dr. HUEPER. You did.

Dr. DARBY. ——is an important factor in the food acceptability. Yet there is no standard way of advertising food which will make the food acceptable to everyone.

Mr. MURER. I think this question can best be answered in this way. The history of the food business in this country is replete with many failures because people forgot that you cannot sell food with an advertising program unless it is acceptable. We have had them in our

company just as well as others, because we did not do an adequate consumer job to see that the food was palatable, acceptable, desirable, and the kind of thing you could sell. In spite of all of the advertising and merchandising, you just cannot make people eat something they do not want to eat.

Dr. DARBY. Do you have any questions, sir?

Are there any additional questions?

Mr. WILLIAMS. Any questions on the part of the committee?

The CHAIRMAN. Does that mean, Doctor, that the public accepts a certain type of food, and the benefit of the advertising program determines whose product is consumed? That will determine that?

Mr. MURER. It is simply necessary to call it to their attention to get people to try it. One may be able to influence them to try it once, but to repeat depends upon the real service that you perform to the consumer. Unless that service is there, the business will not last long.

Dr. DARBY. I think we might very briefly summarize some of the statements or the points that have been made.

It has been pointed out rather clearly that the use of additives is not something which is of recent vintage, that there are technological justifications for the use of additives, and that these can be classified.

Certain additives properly used are justifiable to maintain the nutritional quality of foods; others for the enhancement of the keeping quality and stability of foods which, of course, result in a reduction in food wastage.

Still others are useful in making foods more attractive to the consumer. Finally, they may provide aids in processing of foods.

Dr. Mrak did refer to situations in which food additives should not be used. And I think it is well for us to reiterate some of those. We haven't talked very much about them.

But I think we have all recognized in some of our discussion, that food additives should not be used in foods to disguise faulty processing and handling techniques.

They should not be used to deceive the consumer, and although this has not been discussed I think that one might suggest that they should not be used when their use results in a substantial and important reduction in the nutritive value of foodstuffs.

Mr. WILLIAMS. Is the addition of color deceptive?

Dr. DARBY. I would not include that in the category of deception.

Let me give you an example, if I might. If one is preparing a strawberry jam, and this strawberry jam happens to be prepared by the best possible manufacturing process, and it is of truly high-quality jam, yet in this process there is a loss of color. I think that if one uses color in this situation, one isn't necessarily deceiving the consumer.

I think that you must be able somewhere to draw a line and say that if you are using colors to hide inferior products, then this is considered deceptive.

Mr. WILLIAMS. Would the same thing hold true for the adding of an aroma or odor?

Dr. DARBY. We use many flavoring agents. I would again think this would depend upon the care and the quality of processing. Would someone else wish to comment on that?

Dr. MRAK. I might say we have some quantitative experiments underway in this very area. The matter of acceptance is very complicated. The sugar acid relationship or ratio, as we call it, the

amount of flavor, and the color are all-important. And if we take a consumer panel and we retain the flavor sugar and acid at the same level but lower the color, the acceptance is much lower. Color is a very important part of this total complex. We can do this on foods and we can do it with pure solutions.

Dr. HUEPER. In a gelatine preparation you have color and flavor. The only nutritive value is the gelatine. It is marked on the label that flavor is synthetic, that the color is synthetic.

Dr. DARBY. Which is, of course, one very important way of avoiding deception, isn't it?

Dr. HUEPER. That is right. I would say that it is not deception, but it is not strawberry flavor and it is not strawberry color.

Dr. FOULGER. I think you will find that is due to the housewife pattern. Might I recite an instance where a salmon packer was unable to obtain any red salmon from the fisheries. All the fish he obtained were pale. His competitors received nice red salmon. He did not know what to do until he hit upon the device of labeling the can "guaranteed not to turn pink in the can."

Dr. MRAK. Practicing deception.

Dr. FOULGER. That is a statement of absolute truth.

Dr. PETERS. It might be well to point out that many synthetic flavors are chemically identical with the natural flavors in fruits. The way the chemist discovered how to make many of these was by analyzing fruits and identifying the chemicals nature had synthesized. Now, I have been told, some blends of synthetic flavors are more generally appealing than the natural products.

Furthermore, if we were to insist on the use of natural flavors only, there are cases where there is not enough natural flavor in the world to take care of the uses now filled by synthetics. For example, there are not enough strawberries grown to make all the strawberry flavor that is used today.

Mr. HALE. I suppose there was some use of some chemical additives in foods in early days.

Dr. DARBY. Yes, sir.

Mr. HALE. What were the various chemicals that were used?

Dr. PETERS. Smoke, salt, in curing fish, leveling agents, spices——

Mr. HALE. Do you call spices a chemical additive?

Dr. PETERS. I would think so. Yes, sir. A spice is a nonnutritive additive. I think the general concept in the field in which we are talking is that spices and flavor and colors are all in the same category.

Mr. HALE. I have read of the importance which was attached to spice at the time that Columbus discovered America. Spices were used as substitute for refrigeration, were they not? They could not have had any of the preservative value of refrigeration, but they made food more palatable or it seemed more palatable, is that right?

Mr. MURER. Spices, flavors, and salt actually do have a preservative action and help to prevent spoilage. This is why we salt meat. This originated because of a preservation problem. The fact that we happen to like salt in meat is something which probably was acquired because of this process.

Many of these were used in early years as a better means of preservation.

Mr. HALE. That is very interesting.

Most of the resort to chemical additives at the present time is comparatively recent, isn't it?

Dr. PETERS. Because of the production of mass produced foods, the decline of the suburban population and the increase in the urban population makes it essential. Very few of us can go out and pick a dozen ears of corn in our backyard.

Dr. DARBY. Any further questions on this point? If not, I think we might pass to the next general topic, evaluation of safety. And I believe it has already been pointed out a number of times that in the decisions as to use of chemical additives that safety is an all-important consideration. And I think we might have Dr. Blackwell Smith open this discussion.

STATEMENT OF DR. R. BLACKWELL SMITH, PRESIDENT, MEDICAL COLLEGE OF VIRGINIA, RICHMOND, VA.

Dr. SMITH. I shall be brief, because you showed me the courtesy of hearing me before on this same subject. But I would like to mention about four points which I consider crucial in this matter.

The first is the fact that every additive is a separate chemical, and presents problems which are peculiar to it.

We are concerned about additives because they may have the capacity to produce injury, what we call toxicity.

One sometimes forgets that every single thing that we take into our body as food or as drink, has in some degree, the capacity to produce injury.

The question then becomes not a black or white matter; it is a matter of determining just how much capacity to produce injury this particular substance that we are interested in using has; and then, whether it will be safe when it is used in a particular fashion. In other words, toxicity is a relative matter.

The property of being poisonous is a relative matter. And this property has real significance only when it is considered in relation to a specified proposed use.

The second point I should like to make is that since every one of these additives is a different entity, it is not possible to establish any standardized set of procedures which might be obligatory, which would apply to the testing of all substances proposed for use as food additives. It is necessary for the scientist in each case to be free to design such experiments as he feels may provide answers to the question that need to be answered in that specific instance. Scientists qualified by training and experience should be relied upon to design the experiments needed in each specific case, and then to interpret the data which are obtained from these experiments.

Finally, I should like to say when we establish the safety of a proposed use of a chemical additive, we can only establish practical safety. That is, we establish that it is extremely unlikely that this use would harm anyone, because there still remains some small element of risk. It is my view that additives should confer some benefit upon the consumer in order to justify this admittedly small but nevertheless inescapable risk that is attached to its use. Thank you.

Dr. DARBY. Dr. Deichmann, would you like to speak?

STATEMENT OF DR. WILLIAM B. DEICHMANN, CHAIRMAN, DEPARTMENT OF PHARMACOLOGY, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE, CORAL GABLES, FLA.

Dr. DEICHMANN. Mr. Williams, Dr. Darby, I have been actively engaged in scientific investigations for somewhat more than 25 years, 3 years in industry and the remaining years at the University of Cincinnati, the Albany Medical College, and now at the University of Miami School of Medicine.

Food additives have been used for a long time, and I am quite certain they are here to stay. Therefore, what we really are concerned with is to determine whether a certain compound which is considered as a food additive and which may be ingested for a lifetime by practically all people is liable to induce any harmful effects?

During these 25 years, my assistants and I have carried out many investigations which fall essentially into three phases: Acute, subacute, and chronic studies. Each of these phases plays a very important part in establishing a safe and nontoxic level of a food additive.

As a rule, food additives are ingested. I shall therefore confine my remarks to the oral administration of compounds or food additives to experimental animals.

By an acute study is meant an investigation in which an animal receives only a single dose. Results become apparent almost immediately and the study seldom requires more than a few days for completion.

A study of this type gives us valuable information as to the dose and the concentration which kills, but it also furnishes us with information relative to nontoxic, mildly toxic, and severe toxic levels.

In addition, toxicity studies give us valuable information or hints in regard to the possible mechanism of action, the pharmacodynamics, of a particular compound. Finally, studies like these bring to light pathological changes and other information which are of importance and which are used subsequently.

For an acute toxicity study, generally three species are employed, sometimes more. As Dr. Blackwell Smith pointed out, the number of species to be used depends entirely on the problem. Based on the results obtained from the initial acute toxicity studies, and on the importance of the compound, additional experiments may be set up to investigate in detail, the mechanism of action, and the metabolism of the material.

It is very important that we know what happens to the food additive in the body. But again, let me emphasize that it depends upon the importance of a compound whether the investigation is designed and carried out in as great a detail as I am presenting here.

We must know what happens to the compound, the additive, when it is ingested by an experimental animal, whether it is changed in the intestinal tract, or whether it passes through the body unchanged, or whether it may produce diarrhea, constipation, or other effects during its passage through the body.

It is important to know whether the material might possibly influence the bacterial flora of the intestinal tract, thereby possibly rendering certain drugs, that may be administered subsequently, partially or totally inactive.

It is also important to find out whether such an additive might possibly influence the absorption of certain foods, vitamins, etc.

Next, we must know whether the additive under investigation becomes absorbed into the circulation, whether it is changed by the kidneys, whether it is excreted by the kidneys, or whether it might possibly produce injury to the excretory organs as it is excreted.

It is equally important to determine whether the compound is detoxified by the liver or possibly by other organs. It is essential to learn what these metabolites are that are being formed, and their fate in the body. It is equally essential to determine whether a food additive has an effect upon the blood-forming organs, and other organs that I have not mentioned.

Finally, it is most important to learn whether the compound is stored in the body temporarily, or for a more prolonged period of time.

If the compound is stored, we want to know where it is held, whether it is deposited in the bones, in the liver, in the hair and nails, or in other parts of the body.

It is of particular significance to ascertain whether a compound is stored in the fatty tissues. I am thinking of the body fat, the adipose tissue, and the central nervous system, the brain and the spinal cord. It is of particular importance to know what will happen to a compound that is stored in the fatty tissues in lactating women, or in people who, months later, for some reason should undergo a period of mild, moderate, or severe starvation.

We know from experience that compounds stored in fatty tissues may become mobilized during starvation and that they may induce an acute intoxication long after the ingestion or exposure to the particular agent has ceased.

There are many other tests that could be included in a pharmacological and toxicological investigation, but, as Dr. Smith pointed out—and I should like to reemphasize this—it depends very much on the contemplated use, the maximum daily quantities which may be ingested by a child or by an adult who may be either healthy or ill, and it depends on the toxicity and the specific mode of action, finally also on the financial investments involved that dictate the scope of the investigation.

Subacute feeding tests are generally conducted for a period of 90 days or more. It is our custom to employ rats and dogs primarily for these studies. By means of these tests we determine the maximum daily dose which may be ingested for 90 or more days without producing harmful effects. I shall not go through all the criteria again which are used to measure injury, mechanism of action, and fate in the animal body, except to add this: If it should be found during an acute intoxication that a certain compound produced, let us say anemia, then tests for anemia and related studies will be included in the subacute studies in order to learn the specific small dose of the additive which, when ingested repeatedly will produce this anemia, and what still smaller doses will not produce this effect.

The main difference between a 90-day feeding test and the so-called chronic-feeding studies, which are being conducted at present with rats for 2 years and with dogs for 1 year, is the period of time involved. In my humble opinion, a 90-day feeding test gives us almost

the same information as the 2-year study, except for some information on the possible carcinogenic action of the compound.

If cancer is not produced in a 2-year rat feeding study—conducted over an animal's lifetime—we have some assurance that the compound is not carcinogenic when ingested.

At present, we have studies underway at the University of Miami which are being conducted with three generations of rats and dogs.

Again, let me say that it is the contemplated use, toxicity, quantities liable to be ingested, and the importance of the compound in general which must dictate the extent of a toxicological and pharmacological investigation. Thank you.

Dr. DARBY. Thank you. Dr. Seevers, would you care to speak?

STATEMENT OF DR. MAURICE H. SEEVERS, CHAIRMAN, DEPARTMENT OF PHARMACOLOGY, UNIVERSITY OF MICHIGAN, ANN ARBOR, MICH.

Dr. SEEVERS. Mr. Chairman, Dr. Darby, I can only reiterate and possibly point out in different words some of the statements which have already been made by Drs. Smith and Deichmann.

I think it is important to distinguish in your own minds between the terms "toxicity" and "hazard" and the obverse of the latter—safety.

Toxicity is relatively absolute for any chemical compound and for any animal and for a specific route of administration.

In other words, if we take a new chemical and give it to a mouse by mouth, we can arrive at a toxicity figure which can be reproduced time after time in a group of mice, or we can take the same drug and obtain data for the dog which will probably be distinctively different but also reproducible for that species. In fact, species differences in some instances may be as much as a hundredfold in terms of the amount required to kill.

So, we determine toxicity values for each chemical that comes to us as toxicologists or pharmacologists before we can ascertain whether this compound is safe enough to be used by man.

When we receive it, we do not know much about this chemical substance except its formula, its solubilities, and the like. We go through some of the tests or procedures as outlined by Dr. Deichmann. If the compound is for a certain intended use, we would make certain types of determination using certain types of animal species. If for another use, we would make different types of determinations.

In other words, there is no standard procedure for all compounds.

As you know, in 1938 the present Food, Drug, and Cosmetic Act was passed. My particular field deals with the matter of pretesting for drugs. So that pretesting is not a new situation. It is an old one, 20 years old under our present laws, which have been very useful and well administered.

In the drug situation we have somewhat different standards of safety but the general procedures for determining toxicity and predicting safety are identical to those which would be used for chemical additives to foods. Once we have determined the toxicity of a compound, it becomes our problem to translate this animal data to man. No animal responds exactly the same as man.

We can never predict exactly what the toxicity of a compound will be for man on the basis of animal data. How do we go about arriving at a decision as to whether this substance is acceptable for use in man?

Having before us toxicity data which we have determined for several animal species we allow on the basis of our previous knowledge relating to toxicity of certain classes of chemicals a factor of safety which accounts for animal variation. If we find, for example, or have a basis of common knowledge, that a certain general class of chemical substances has a certain toxic level for the dog, and the toxicity for man is reasonably comparable, we would guess that other members of this class of chemical substances would have a similar toxicity for man.

This is our first type of calculation. Since we are dealing usually with toxicity studies on several animals, we take into account all of the data on all of these species and arrive at a figure for man which is based on animal determinations alone.

Then since we know that all men do not react the same to any chemical, that there are weak men and strong men, we put in a large factor of safety to account for this element of variation.

In the case of many drugs, and certainly those chemicals which are to be added to foods, this may be a hundredfold factor of safety, saying, in effect, that a man who is weak might be able to take one-hundredth as much of this material as a man who is strong.

In some instances this factor might be much larger. Once the predicted tolerated dose for man has been arrived at by a series of intelligent guesses—and I must admit that this is about the level of our present status—we then cautiously try this drug in man. If we find no evidence of toxicity and the use is satisfactory for which it is intended, after a preliminary clinical trial this drug then goes into the open market.

The principles which I have outlined are exactly those which must apply to chemical additives, recognizing the fact that no animal data will ever permit us to predict exactly what occurs in man, and that substances that are added to foods are going to be used continuously. We allow a much larger factor of safety for substances which are to be consumed regularly since this will be a constant bombardment to the physiological processes of that individual.

One of the cardinal principles of toxicology is that every substance has a "no effect" dose and every substance also has a toxic dose. This is saying in simple words what Dr. Smith has already outlined to you.

In other words, we can take any compound and dilute it out to a concentration where it may be ingested without any harm whatsoever. We can even do this with radioactivity.

All of us are exposed to a certain amount of radioactivity regularly although it is a very low tolerance level. But there is a tolerance level for every compound including the so-called carcinogenic agents.

There is no evidence in the literature that chemicals which have been shown to produce cancers in large concentrations in animals are capable of producing these animal cancrs at levels used in human food. Obviously, if we raise the dose a thousandfold, injury may occur.

The same thing is true of other types of toxicity, degenerative diseases, and the like. So that we finally arrive at a situation in which

we are talking in strictly quantitative terms; and safety is a quantitative term always, and it will never be anything else.

The hazard, therefore, of a chemical compound for man can never be defined in absolute terms and it is never possible to state that any chemical substance is absolutely safe. The best we can ever expect to do is to arrive at a situation in which we can make an intelligent guess on the basis of a large amount of experimental data.

One of the other fundamental principles is that the person who is making the toxicological examination or the person who is responsible for evaluating these data—and in this instance, this would apply not only to the original investigator but also to the people in the Food and Drug Administration who ultimately are charged with the responsibility for making these decisions—should not be tied by any standardized procedure. Their hands should not be tied as to the type of tests that they shall ask for in determining toxicity or predicting safety.

Obviously if we were to go through all of the procedures as outlined by Dr. Deichmann and some procedures which have been proposed which would involve 10-year experiments on dogs and monkeys, for example, and do this for every chemical substance that is used as a drug or as a food additive or whatnot, we would soon reach a stage where we would not have any drugs or any food additives, because the cost of this type of procedure is prohibitive.

We have to, therefore, use commonsense in our approach and keep perspective between what we know about toxicity and how we evaluate safety. As has been previously indicated, it is impossible to say a priori that any compound has absolute safety for man.

I think any scientist who stood up and said that any compound, including those added to food or drugs, is absolutely safe under every circumstance would be obviously in error.

Even safety is not standardized. There are different levels of safety requirements. In the drug field, for example, no one would accept a high-toxicity level for a mouthwash or for a painkiller which was sold over the counter. The standards for those are low toxicity and a very high degree of safety, because the person who buys a drug over the counter has only before him the label on which to judge the potential injury that may be caused by this compound.

The same thing would apply to chemical additives for foods. So that substances that go into foods must have, obviously, a high safety level. On the other hand, in medicine, if we have a disease which is a hundred-percent fatal, such as certain types of cancer or leukemias, we are justified in using compounds which are very highly toxic, and actually do use compounds which have been known to kill.

Safety is only a relative matter, whereas, toxicity itself is a fairly standardized qualitative as well as quantitative value for any animal, including man, for every drug and for the method of administration.

In the food situation I am sure that the criteria of safety will never be entirely standardized. Today we have a great surfeit of food. If we had only 50 percent of enough food to supply the American population and 50 percent of this was spoiling, I am sure that our standards of safety for preservatives would be much less than they are today.

Where safety is concerned the criteria vary with the problems that we have at hand. And I think I could summarize by saying that it is extremely important to distinguish between toxicity and hazard as they relate to safety. And if I can make any contribution, I think that is the most important one.

Dr. DARBY. Thank you, Dr. Seevers.

Dr. Smyth.

STATEMENT OF DR. HENRY F. SMYTH, JR., MELLON INSTITUTE, PITTSBURGH, PA.

Dr. SMYTH. Thank you, Dr. Darby.

I have been studying toxicity for industry since 1927. The first 10 years I practiced as a private consultant. In that period there were 52 chemicals upon which I made toxicological studies for 1 chemical manufacturer.

My first study of a material which we today would call an incidental food additive was in 1931. Late in 1937, I went to Mellon Institute, my present organization, to set up studies of what we called toxicology, to be completely supported by Union Carbide Corp.

The team which I have built up there at Mellon Institute is essentially the experimental toxicology department of Union Carbide.

We are expected to advise that corporation and its customers what intended use of new chemicals will be safe and proper.

Included in that is, of course, food additives. It happens because of the nature of the products of that corporation that most of those additives would be classed as incidental additives, not added to the food on purpose to change the quality or characteristics of the food, but to facilitate food production through which a small amount remains in the final food.

That is an irrelevant distinction in my mind. If a chemical is in the food, it doesn't make any difference to the eater whether it was put in there to change the food or whether it just happened to be there, because it was used to make the food production simpler.

There really is not any difference from the point of view of the safety or hazard based on the reason why it is there. Our studies are necessarily step-by-step operations, becoming more and more detailed and refined as we proceed with a particular chemical.

The amount of work which will be done on the chemical, of course, has to be proportioned to the profit which the corporation expects to make from the chemical. The market which the corporation foresees where that chemical might fill a need is also considered.

Now, if a very small market is foreseen, we do not do detailed work on the chemical. Neither do we offer a chemical for food uses or other uses where there will be large public risks. If we were going to offer it for such widespread public contact, then probably the market would be big enough to justify the expense.

But there have been many instances where the sales department has decided that the potential profit from a chemical would never cover the cost of our detailed studies. In those instances, the studies we make are sufficient in our opinion to allow us to determine how this should be handled in its manufacture, how it should be handled by the customer who might be using it to clean metal parts before plating, or some other

industrial use. They are not sufficient to determine safety in exposing the whole population, as a food additive. This chemical is never offered for such uses, exposing the whole population.

It is sometimes lost sight of that the expenses of demonstrating whether or not a particular use of a chemical is safe must be paid for out of profits on that chemical or other chemicals made by the same corporation. The way that is done, I repeat, is that when you are quite sure profits on a chemical can never be sufficient, then you do not offer it for uses which require detailed longtime proof of safety, because you are going to be exposing a tremendous part of the population without their voluntarily electing to be exposed, as you do in foods.

We must injure animals in our work with each chemical to study it thoroughly. We must injure them so that we can determine what is the nature of the injury to animals, and estimate from our experience and the work of others what would be the likely injury to humans from that same chemical.

In the food acceptance work, determining whether or not a particular use of a chemical in food technology would be safe, we go further than determining the nature of the injury. We try to estimate, much as Dr. Seevers discussed, what would be the dose tolerated by the man, the varying population of the country, varying intakes and varying susceptibilities.

We study the changes that take place in the chemicals in the bodies of each kind of animal in our laboratory that is convenient to study. Then we do sufficient exploratory work on humans to determine how the human body changes this chemical. The species of animal which changes it in the same way that the human changes it is the species which gives us the best prediction of how much a human can stand.

That is saying over again very much what Dr. Seevers said on his translation of our animal results to human results. I have not read earlier testimony before this subcommittee, but some earlier witness said that industry does not do very much toxicity testing of its chemicals. That, I believe, was based on lack of information.

The Food and Drug Administration published results on its first 2-year period of feeding a chemical to experimental animals in the year 1942.

Because of frequent conferences with Dr. Calvary, who was then principal pharmacologist, I knew that work was underway. I was interested in it. We had started ourselves our first such 2-year feeding study in 1940. It was not completed by the time the Food and Drug Administration published their first results.

I might say that we speak loosely of a 2-year study. It takes 3 years to do a 2-year study, because when it is over, it takes a year to go over the notebooks and study the slides and decide what you have found out by feeding these animals for 2 years.

Since that time, my team at Mellon Institute has started 23 such studies. It is pretty generally accepted today that although we do not have a standard pattern for testing the safety of chemicals entering food, nevertheless, unless there is good reason, we are very likely to stick to the 2-year rat doses and 1-year doses to dogs, which Food and Drug stresses.

Each one of those starts has committed us to spend between forty and fifty thousand dollars on that chemical, unless we give up and

say it is obviously too toxic and it cannot possibly be shown safe, in which case we will stop short.

Fifteen of them are completed, and 14 have been published. I think I am right in those figures. That is an important point, as I will come to in a moment. Four of them are still in progress. Four of them were terminated early because the decision was that the compound would not be safe in the proposed manner of use.

It does not mean it would be too toxic ever to use in foods, but it will be too toxic in this particular manner of use involving a quantity and a frequency.

My lawyer contacts have told me that the act of 1938 does not put a burden on the user of a new chemical to prove it is safe. I naively have always felt that it did put a burden on me at least to satisfy myself that any use proposed for a Carbide chemical was safe, and to some extent to see, to the small degree in which I have authority, that the customers use the compound safely, without endangering the public.

One of the problems in advising customers how they might use products and what they might use them with is knowing what other chemicals have been adequately proven safe.

It may be general knowledge that a given food additive, a given chemical, is entering food. But a search of the medical literature does not reveal any evidence that it has been proven safe. Nevertheless it is general knowledge, and there is every presumption, that the Food and Drug Administration, in informal conference has said we will not object to this use, it appears to us to be within the law. The evidence may not be published.

I feel that that is wrong. As a toxicologist and a specialist in public health, one phase of public health, I feel that any decisions which affect the public health should be based on facts which are generally available for scrutiny by all qualified persons. They should not be based on private information.

I am not enough of a lawyer to know how that can be accomplished. It is my understanding that it cannot be accomplished today. But I do not like to think that my family, my children, my friends are getting food with X material in it, where I, as a qualified person, qualified to form judgments, cannot find anywhere in print what was done to prove that that use of that chemical was safe.

Now, a little digression.

We talk a lot, toxicologists and others discussing chemicals in food, that is, in terms of numbers. We talk about parts per million. I do not believe that anybody has a clear concept of what a million is.

Well, what is one part per million? That is a good figure because many of the pesticide tolerances are on the order of one part per million.

What does it amount to?

In units you can visualize that if you take a drop of water—and to the apothecary, a drop means something very definite—they used to call it a minimum—he now calls it 0.06 milliliters. It is what drops from a standard medicine dropper that we put in our eyes. We put 1 drop in 16 gallons. You have one part per million. What is 16 gallons? Well, it is 80 fifths of whiskey, which a good many people can visualize. That is one part per million. I like to visualize things

in terms that I can conceive of handling. I get some concept of what the numbers mean.

Thank you, Dr. Darby, that terminates what I have to say.

(The following additional information was later received from Dr. Smyth:)

MELLON INSTITUTE,
Pittsburgh, Pa., October 4, 1957.

Mr. JOHN BELL WILLIAMS,
Member of Congress, Chairman, Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce, Washington, D. C.

DEAR MR. WILLIAMS: I wish to take advantage of the committee's permission to extend the remarks made in my testimony of August 6, 1957, upon the subject of chemical additives in food.

Toward the end of my testimony on that day I said, "I feel that any decisions which affect the public health should be based on facts which are generally available for scrutiny by all qualified persons. They should not be based on private information." It now seems to me that I did not explain clearly what I had in mind.

Under the Miller amendment to the Food, Drug, and Cosmetic Act of 1938 (sec. 408), I understand that the Food and Drug Administration is free to establish a tolerance for a pesticide on raw agricultural products upon the basis only of its interpretation of a manuscript copy of the report of a toxicological study furnished by the petitioner. That report may remain in what I believe is called a commercially confidential file in the offices of the Administration. I understand there are severe penalties awaiting any employee of the Administration who reveals the contents of a report in this file. There is no obligation for the author of this report to publish his work in the scientific literature.

Once the tolerance has been established, the pesticide may enter the food supply of the country in an amount which the Administration concludes is safe. There may be no way for the scientific community to judge whether the conclusion of the Administration is sound, or whether it is in error.

Scientists expect to be able to scrutinize the methods, results, and conclusions of their colleagues in the form of published articles in the scientific journals. Until there has been opportunity for all other scientists to apply their own special knowledge to published conclusions, and if desired to repeat the published studies, these conclusions are not regarded as necessarily established or acceptable. It seems to me particularly important that decisions which result in adding a new material to the food supply, and hence which may affect the public health, should receive the fullest possible scientific scrutiny and judgment. It is not enough that a group of Federal employees, however qualified and devoted to public welfare, shall judge that the addition is safe.

This can be accomplished by requiring that the scientific evidence for safety of the use of a new food additive shall be published in the scientific literature before the additive reaches the country's food supply. In the interest of a balanced view, I should state that I believe the majority of the toxicity reports upon which pesticide tolerances have been so far based are already published, but there has been no obligation to publish them.

I believe that the public health likewise required the protection of general scrutiny in respect to additives other than pesticides. Most proponents of these materials now confer informally with the Food and Drug Administration before they market a new additive. Their proof of the safety of proposed uses may end up in the commercially confidential file and may never be published in the scientific literature, just as with the pesticides.

I have been told that the evidences of safety are private property, having been paid for by private money. I concede the truth of this view up to the time that a new additive is about to reach the food supply. At that time the additive is capable of injuring all of us, should it be used in too great an amount, and I think that the public interest takes precedence over proprietary rights and commercial secrecy.

I understand that the new drug provisions of the act of 1938 provided for commercial secrecy of some details bearing on the safety of drugs. I find this acceptable as regards new drugs. The physician who prescribes a new drug should be well aware of the tentative nature of the proof of its safety, he is alert for evidence of adverse side reactions in his patient, he is able to with-

draw the drug from the patient at the first hint of a bad reaction. Once a food additive is judged to be safe, it is used without close scrutiny. Should adverse effects result, it is probable that they will not be known promptly. Withdrawal of the additive from the citizen who experiences a bad reaction may not take place promptly. Because of the competence, alertness, and responsibility of our physicians, we can tolerate a less rigid proof of safety in new drugs than in food additives.

My experience does not equip me to draft a provision which will incorporate into the law the safeguards respecting publication of evidence for safety which I believe are required to protect the public health.

Very truly yours,

HENRY F. SMYTH, JR.,
Administrative Fellow.

Dr. DARBY. Thank you, Dr. Smyth. Dr. Spencer.

STATEMENT OF DR. HOWARD C. SPENCER, BIOCHEMICAL RESEARCH DEPARTMENT, THE DOW CHEMICAL CO., MIDLAND, MICH.

Dr. SPENCER. Mr. Chairman, members of the committee, Dr. Darby, my name is Howard C. Spencer. I am employed by the Dow Chemical Co., Midland, Mich., in the biochemical research department. I came to Dow in 1937 and have been associated with the biochemical research department since that time, first as a biochemist and animal pathologist in the toxicological laboratory, and later in charge of toxicological research. At present I am in charge of food research for the company.

I received a doctor of philosophy degree in biochemistry and a master of science degree in physical chemistry from the University of Nebraska, and a bachelor of arts degree from the College of Emporia in Kansas.

Our laboratory has been actively engaged in toxicological research for more than 20 years. We not only carry out work in our own laboratory, but we also sponsor work in university and consulting laboratories.

The problems presented to us are very similar to the problems that have been discussed by Dr. Smyth. In general, the operation of our laboratory follows the same pattern that Dr. Smyth has so ably presented.

Broadly speaking, we in the toxicological laboratory at Dow are vitally concerned with the safety of human beings.

In the first place, we make certain that chemicals are produced safely. Thus, we obtain the toxicological information necessary to define and describe conditions for the safe manufacture of materials.

Second, we are concerned with the safe handling of chemicals. We are definitely concerned with the safe use of chemicals by people. Now, of course this is very broad, and the matter of food additives is only one of many possible uses for the broad spectrum of chemical compounds.

I would like to use one example that has not been used here. This is our concern over the safety of the large group of compounds that we commonly call pesticides, which are materials that you are familiar with—insecticides and fungicides necessary in the production of food crops. In the case of these materials, we conduct laboratory work showing the conditions under which they can be manufactured safely and handled safely by the farmer and orchardist.

Then we are concerned with the incidental residue that may appear on the raw agricultural product. In this connection, of course, we operate under the Miller amendment. I believe no more needs to be said other than pointing out that a great amount of work, such as that described by Dr. Smyth, is done on this broad group of materials.

In the development of new products that may be useful in the food industry, such as the products that have been described by Dr. Mrak, Dr. Peters, Dr. Murer, and others, we realize that a great deal of basic toxicological information must be obtained so that we can judge the safety of specific uses of these materials.

In this connection, there are many cases in our experience, as I am sure in the experience of other companies, where potentially useful materials have been ruled out on the basis of toxicological data showing them to be unsuitable for certain uses in foods.

This principle of pretesting is firmly established in the chemical and food industries as shown by the work in industrial, university, and consulting laboratories. In other words, the safety of a food additive must be established prior to its use. These necessary laboratory investigations that have been discusesd and described by Dr. Smith, Dr. Deichman, Dr. Seevers, and Dr. Henry Smyth call for the combined efforts of men with diversified training and experience.

In our laboratory we have men with basic training in chemistry, biochemistry, pharmacology, phsysiology, nutrition, pathology, veterinary medicine, human medicine, and other sciences. These men work as a team. They work not only as a team familiar with the sciences but they also must have practical experience in the field of toxicology.

Furthermore, they must have practical experience in the interpretation of laboratory data in terms of safety to man. I would say in all of this work—and I believe that this point was also made by Dr. Smyth—that it is the responsibility of trained and experienced scientists to design and to carry out those particular tests which, in their best judgment, will give adequate data upon which a sound judgment can be made as to the safety of specific uses of the material under investigation.

I am sure that this point was made very well by the previous speakers.

Also, as the previous speakers have pointed out, these laboratory procedures are not stereotyped. They can never be drawn up in a cut-and-dried cookbook fashion. There are limitations and variations in all procedures.

I would like to add that I firmly believe that no stereotyped set of procedures can replace the considered judgment of well-trained, experienced men responsible for the design and carrying out of experiments.

In all of these considerations it must be remembered that toxicological studies are based upon the cardinal scientific principal that for every substance there is a no-effect dose as well as a toxic dose. This principle has been ably discussed and supported by Dr. Smith, Dr. Seevers, Dr. Deichman, and Dr. Henry Smyth.

Further, I would like to emphasize the statements that have been made by many others that properly designed and executed laboratory experiments can provide an adequate basis for judging with reasonable assurance the safety of specific uses of materials.

Dr. Seevers, I think, made this point well. We all recognize that there is no such thing as absolute safety. It is a relative matter. But I think we should always remember that the present state of knowledge in the various sciences of toxicology, pharmacology, and pathology enables us, with reasonable assurance, to arrive at a decision as to whether a specific use of a material is safe or unsafe.

Just as the design and conduct of the experiment is the responsibility of the scientists, the team that is charged with the responsibility for obtaining the necessary toxicological information, so also is the evaluation or the interpretation of these data.

I believe that sometimes scientists may overlook this fact. Nevertheless, it is my firm belief that scientists, as a group, are in the best position to evaluate the data in terms of actual safety to man. I would like to give a pertinent direct quote here. Dr. Lehman, chief of the Division of Pharmacology, Food and Drug Administration has said:

> **There can be no formula, ratio, or substitute for the mature and considered judgment of men fitted by experience and training for making the final recommendation. In the last analysis, the caliber of the men conducting the experiments and making the evaluations determines the usefulness of animal toxicity data (Lehman, A. J., et al., Procedures for the Appraisal of the Toxicity of Chemicals in Foods, Drugs and Cosmetics, Food Drug Cosmetic Law Journal, vol. 10, No. 10, pp. 679–748, October 1955).**

I believe that this is very true. It depends firmly upon the men conducting the experimental work and their considered judgment as to the safety of specific uses.

I would like to make one further point. I feel that each of us has a very real responsibility to continually study the methods that we use, to examine and to reexamine these methods, and to consider them in the light of the scientific literature and in the light of advancements that are made in the scientific fields. We should try to develop other approaches to the problem, without discarding the good tests we have. Thus we should consider how we can approach the problem in even a better way, so that we can give even greater assurance of the safety of the use of chemicals.

This is true whether we are associated with an industrial concern, an academic institution, or with the Government.

I feel that this obligation is one that scientists are accepting. I am happy to report, Mr. Chairman, that men in this field are accepting this responsibility and are giving increasing thought to the basic scientific problems involved.

Thank you.

Dr. DARBY. Thank you, Dr. Spencer.

Thus far the discussions on the evaluation of safety have dealt primarily with what we might term laboratory evaluation of safety. On the panel is one man who has had particularly wide experience in the field of work with human subjects. I should like, if I might, to call on Dr. Foulger to present that aspect at this time.

STATEMENT OF DR. JOHN H. FOULGER, DIRECTOR OF MEDICAL RESEARCH, E. I. DU PONT DE NEMOURS & CO., WILMINGTON, DEL.

Dr. FOULGER. Mr. Chairman, Dr. Darby, I am a physician who has been engaged in scientific research for 37 years. For 29 years I have studied the action of chemicals on animals and on humans. For 22 of these years I have had a direct and continual responsibility to advise the Du Pont Co. on the hazards to health which the chemicals they manufacture or handle in their plants might afford their workers and their customers' workers and the general public.

In obtaining information, I have been a member of the staff and eventually director of the Haskell Laboratory for Toxicology, situated in Newark, Del. It has been my duty to advise our design engineers on the construction of safe plants, to advise our safety men on the allocation of proper physical protective devices needed in cases of breakdown of equipment on those plants, to set up proper programs of medical examinations of the workers so that we can decide whether our physical protection and the structure of our plants are really protecting workers against injury to health by the chemicals they handle.

In addition, as the results of studies in our Haskell Laboratory, we must correctly label our compounds in accordance with Interstate Commerce Commission regulations for class B poisons, the Federal Pesticide Act of 1947 and, of course, we must conform when our chemicals are insecticides or when they become additives to be used in the food field, to the Food and Drug Act of 1938.

Since 1939, I and my associates have had continuous exchange of information and mutual planning of testing with the Food and Drug Administration, Division of Pharmacology, first under Dr. Calvary, whom I knew personally before he joined the Federal service, while he was on the staff of biochemistry at the University of Michigan and later with Dr. Arnold Lehman.

Having heard what my colleagues in this field have said on the matter of testing on animals, I think the best contribution I could make to this panel is to give you some idea as to what has happened over the years to humans exposed to chemicals. The impression has been given that even these small quantities of chemicals in food additives over the years are producing deterioration of health and may be producing new, unobscure disease.

Now, in making such statements, it has been forgotten that the field of industrial medicine has developed parallel to the field of industrial toxicology and the entrance of chemicals into all parts of our daily life. I have had an unusual opportunity in 22 years to see thousands of men exposed to chemicals on plants. The significance of that opportunity is this:

These men as citizens eat the same foods as those not in chemical plants, therefore, if there is any hazard from chemical food additives, these men are in the same jeopardy from that hazard as are the rest of the population not in chemical plants.

In addition, however, in spite of all our attempts at protection, many of these men in our plants, day after day, by inhalation of

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fumes, or dusts, or gases, or mists, or by contact with equipment through which many chemicals have passed, are taking into their bodies quantities of many of the same chemicals that people are scared about as additives far greater than those which they would ever take in eating their daily food.

Those men, therefore, are under double jeopardy with respect to the effect of the intake of small quantities of modern synthetic chemicals upon their health. Now what has happened in the last 20 years?

There are two phases we must watch for in industrial medicine. First of all, manifest injury to our workers by industrial operations is controllable by the State industrial compensation acts. The number of cases in which men are injured by chemicals in our plants and become industrial compensation cases has continually decreased. But it so happens that within our company we are able, also, to follow the health of the workers when it is affected by disease or illness not of industrial origin.

Since 1937, the worker in the Du Pont Co. after 1 year of service is entitled to come under what we call our disability wage plan. When eligible, if he should be sick from disease of nonindustrial origin, he gets full pay while he is sick for at least 3 months and in extreme cases, if it should be a sickness such as tuberculosis, that period may be extended.

We have records of time lost for sickness of this type over the years and in preparation for this panel I went over very roughly, from data in my files, the company's record for 17 years, 1940 to 1956 inclusive, and the records of a number of specific chemical plants also.

In 1940, the average days lost for nonindustrial sickness for an employee under this scheme was 7. There were about 45,000 men covered. This average rose during the war years to a peak of about 12 in 1946. When the war effort was over and things got back more or less to normal, the average dropped very rapidly and during the last 4 or 5 years there have been about 5 days lost per man per year. That is a very low figure.

This does not indicate a cumulative effect of years of exposure to chemicals in food.

Why did the average rise to a peak during the war? There are a number of reasons. First, during the war we were forced to employ people of a physical condition which we would not normally employ in hazardous operations, because we were more or less reaching the bottom of the barrel and had to put so many of our men into war plants which we were operating for the Government. Second, during the war years it was often necessary to put men on double shifts, adding to their fatigue and to their exposure to chemicals. During the war years, it was extremely difficult to find housing—the big housing boom had not begun. During the war years, all over the country where there were big industrial organizations, it became extremely difficult for a man to obtain adequate, good food. As a matter of fact, quite often on the West coast in some war plants conducted for the Federal Government, men would take a day off in order to drive miles into a city to get a square meal.

When these war stresses were over, the number of days lost for nonindustrial sickness fell.

Again, when I began to compare what had happened in plants in which I knew that, in spite of our efforts, there was a possibility of exposure to hazardous chemicals with the experience of plants in the same vicinity and, therefore, with the same cross section of the population coming from the same counties, eating the same food, having the same transportation difficulties, I found there was no relationship between the health pattern and the possible intake of chemicals men were exposed to and that might include some chemicals which are used as food additives. The total pattern of these plants was the same as that for the total company.

There is no proof that over the last 17 years there has been a deterioration of the health of the people as shown by our study of 50,000 workers.

Dr. Seevers talked about relative safety. In 1956, the average lost time for nonindustrial sickness of those 50,000 workers was 5.2 days. In 1956, 40,000 people lost the rest of their lifetime by death on the highways; 26,000 people lost the rest of their lifetime, not 5.2 days, by death at home, mostly by falls; 14,000 people lost their lives in industry, not just 5.2 days.

Since the beginning of my study in 1940, on the average 30,000 people have been killed on the highways each year, a total of 370,000 people.

Seventeen times 25,000, which is 425,000, have been killed in the homes, and 17 times 12,000, or 204,000, people have been killed in industry.

Since 1940, out of 50,000 workers, the accumulated lost time for sickness of nonindustrial origin, on the average, has been 126 days, not a lifetime. Those are comparative figures on safety.

Despite what I have said, I maintain—and it has been our position for years—that anything which goes into food or, in fact, any chemical which is handed to the public for any use whatever, should be tested for safety.

The test, of course, would depend upon the use. One cannot determine a pattern for all chemicals. That is extremely important for this reason: We are interested ultimately in the health of the people and not in the health of white rats. It happens that at this time we must for obvious reasons do our testing on laboratory animals. It so happens that because this is a relatively new science we have not yet devised methods of studying those laboratory animals comparable to the methods which we would apply to humans in modern clinical investigation. But in the next 4 or 5 years, as I see the advancement of testing both in clinical medicine and toxicology, we shall develop such methods. For that reason, it is absolutely essential that nothing whatever be done to freeze a testing program in any way. That could be disastrous to the people.

My reason for this statement is this: There has been an amazing change in medicine in the last 15 or 20 years. It really started with the sulfa drugs, which were introduced here in 1934, and, of course, it has extended with the antibiotics and will go on. That change in the character of medical practice and therapy has had its influence, also, on medical diagnosis.

We are not now dealing with those diseases of humans to which would apply the old dictum of the pathologist that a specific disease

was produced by a specific cause and had a specific pattern of injury to a specific tissue.

We are no longer dealing with those diseases. We are dealing with the diseases of stress, the continual insults to the body, to the functions of the various parts of the body produced by our modern life; by such things as worries in the home; financial worries; fear of being sick; difficulties of housing; difficulties of driving on modern crowded highways over holiday periods. These stresses we now know have a terrific effect upon the body economy and if repeated often enough can lead to disease.

I will say as a physician, who has studied this problem and from knowing what happens and from what reactions men in our plants show under these same stresses, that the apprehension that is being produced in this country in the last 10 years by scare headlines on the effect of food additives could well have had a more injurious effect upon wide sections of our populace than can any additive in use or any additive which we may think of using.

Whatever additives are used will be tested. It may be that the testing is on a voluntary basis now, but should it be mandatory, we would like that, provided we are free to adapt our knowledge in the field of medicine to our program of testing in the field of experimental animal toxicology. Thank you.

Dr. DARBY. Thank you, Dr. Foulger.

The CHAIRMAN. Mr. Chairman, it is now 12:15, and I understand the panel will not be able to sit this afternoon.

Mr. WILLIAMS. I do not think the committee will be able to sit this afternoon either. There is legislation scheduled on the floor, as you know.

The CHAIRMAN. I wonder if I might inquire of Dr. Darby at this time what he has in mind with reference to further presentation.

Dr. DARBY. We would like, if we might, to have one more person speak to this subject, and then open this subject of toxicity for discussion.

We can do that today if you could meet this afternoon. We are at your disposal. We will be able to continue tomorrow. So, we await your decision.

The CHAIRMAN. Following the completion of this particular subject matter, do you have other subjects?

Dr. DARBY. Yes. We should like to have about four persons discuss or introduce the subject of carcinogenesis tomorrow and then open that for discussion.

The CHAIRMAN. Do you have another subject?

Dr. DARBY. No. Then any general discussion would conclude our presentation.

The CHAIRMAN. I am merely trying to find out what the general program was, Mr. Chairman, so that we can determine the schedule of the committee and decide what we would be able to do to meet your convenience.

It seems to me with that program we should be able to complete that in the session tomorrow morning.

Mr. WILLIAMS. Even if we fail to conclude this tomorrow morning, do you think the panel might be available tomorrow afternoon for discussion?

Dr. DARBY. Some members of the panel would be, sir.

I believe there are two members who have a commitment that would make it impossible for them to be here; at least two members; and there may be more. I have not actually polled them on that, sir. I should be glad to do so.

The CHAIRMAN. I think the question is very appropriate, because the bell is now ringing.

Mr. WILLIAMS. Yes, the bell is now ringing for a call to the House.

Mr. O'HARA. We might not finish with the panel tomorrow morning. I wondered if it would be possible for at least some of the panel to return for the afternoon.

The CHAIRMAN. Yes. He said that would be possible, with the exception of 2 or 3 members of the panel.

Mr. WILLIAMS. I would like to ask the members of the committee to make every effort to be here on time in the morning if possible, because we have a long session in the morning ahead of us.

In view of the fact that the bells have rung for a call of the House, the committee will stand adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 12:15 p. m., the subcommittee adjourned, to reconvene at 10 a. m., August 7, 1957.)

FOOD ADDITIVES

WEDNESDAY, AUGUST 7, 1957

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to recess, at 10 a. m., in room 1334 New House Office Building, Hon. John Bell Williams presiding.

Mr. WILLIAMS. This morning the Health and Science Subcommittee of the Interstate and Foreign Commerce Committee continues its panel discussion on the subject of food additives.

I think I can speak for the members of the subcommittee when I say that yesterday we felt that we had a very enlightening session, and we feel sure that today's session will be a continuation of that.

Again I wish to thank you, Dr. Darby, and your associates on the panel for taking the time and trouble to come before the committee and discuss this very important matter with us.

At this time I will turn the session over to you, Dr. Darby, as chairman of the panel, and I suggest that you proceed as you feel best.

STATEMENT OF DR. WILLIAM J. DARBY—Resumed

Dr. DARBY. Thank you, Chairman Williams.

It might be well, sir, if I attempted to summarize very briefly some of the points which were made in yesterday's discussion.

In the later part of yesterday morning, a number of the panel members pointed out rather clearly that it is necessary for us to continue to use chemicals in the production, processing, and storage of foodstuffs. Furthermore, that the additives which are in use and probably will continue to be in use include a very broad group of substances.

Several of the panel members also reviewed, and I think indicated quite clearly, that there are methods of assessing safety; that these methods have been and are being employed in the study of additives.

A number of these procedures were outlined. It was repeatedly emphasized by the participants that each additive, each chemical additive, is a different substance, and, therefore, it presents certain differences in judging the results of testing and in expressing judgment on the safety for the particular use or uses for which this additive is proposed.

It would seem that in any regulatory procedure there should be an allowance for what we might call individuality of additives—individuality of appraisal of safety. It was further pointed out that

one cannot judge safety without some knowledge of the use to which an additive is to be placed.

Safety is not isolated, then, from use. It is necessary to have some concept of use, regularity of appearance in the diet, and so on, in order to appraise the problem, or in order to appraise or to judge safety.

I am not certain that in yesterday's discussion it is sufficiently clear, or that a differentiation was made between use and usefulness. No doubt this will come up in the discussion, but I believe we should bear in mind that "usefulness" and "use" are really two different concepts. They are two different words.

It is essential for any scientist who is attempting to appraise safety to know something of use.

Mr. WILLIAMS. Doctor, some of these bills refer to "functional value."

Is that what you are speaking of?

Dr. DARBY. If I might give my personal interpretation of functional value, I think that functional value and usefulness are much more the same than are usefulness and use; that is, use means actual incorporation in food.

Mr. WILLIAMS. When you refer to usefulness, you are alluding to the functional value, so to speak?

Dr. DARBY. Yes.

I think, further, that several of the panel members expressed repeatedly the scientific nature of decisions or judgments as to safety, and, therefore, the need for scientists to make judgments in this area.

Now, at the end of the morning, we had reached a point of discussing the type of evidence which might be available from a study of man himself.

I should like to call on Dr. Levin this morning to continue this discussion, if I might.

Following his discussion, we will open this to general questioning and comment. And just as we begin, Dr. Levin, I might remind all of us that we are hoping to stay rather closely within our time limit this morning, because we would like to get as much time for discussion as possible.

Dr. LEVIN. Thank you, Dr. Darby.

STATEMENT OF DR. MORTON L. LEVIN, ASSISTANT COMMISSIONER, DIVISION OF MEDICAL SERVICES, STATE DEPARTMENT OF HEALTH, ALBANY, N. Y.

Dr. LEVIN. Since this question has possible relevance to the occurrence of cancer in man, what is known about the causation of cancer may have pertinence to how one might evaluate the possible carcinogenic effect of materials such as food additives.

The first point I would like to make is that as far as we now know cancer is a disease with multiple causes; that is, the same type of cancer can be produced by several different agents.

For example, one type of cancer can be produced to a number of chemicals, by exposure to radiation, by association and preexisting other disease, and by hereditary factors.

In spite of the fact that multiple causes of cancer are known in man and in animals, we do not have any common denominator for

these causes. Although all carcinogenic agents are considered to be irritants, many irritants do not cause cancer; we do not know why some chemicals do, and others do not, produce cancer under the same conditions.

For that reason we cannot predict whether a new agent will or will not be causative of cancer in man.

In other words, we cannot exclude, on the basis of what we already know about the causation of cancer, some new type of causative agent. Secondly, in spite of the fact that we know something about multiple causes of cancer in man, in most of the common cases of cancer that occur in human beings, we cannot identify any one of the known causes.

In other words, most cases of cancer are of unknown causation as far as we know. The relevance of that is that in the United States cancer will affect 1 out of 4 individuals at some time during life.

In other words, it is a common disease.

In the presence of a common disease, of which most cases are of unknown causation, I think you can understand the sensitivity of physicians and public health authorities to the possibility that substances which we do not suspect today may be causative of cancer.

In other words, we cannot rule out the possibility that seemingly innocuous substances on the basis of general experience may turn out to be significant for cancer when studied thoroughly.

Now, with respect to the chemical causes of cancer, it is interesting to note that this possibility was originally discovered by observation of human beings. The first such observation goes back to 1775, to the observation of a British surgeon that persons in the occupation of chimney sweeping in England were prone to scrotal cancer, attributed, and we now know rightly so, to exposure to coal soot.

As a result of extensive laboratory investigations made since 1920, several hundred carcinogenic chemicals are now know, most of which have not been tested in man because no one would want to test deliberately a know carcinogenic chemical in animals or man.

However, a number of chemical causes in men have been discovered, not by laboratory work primarily, but chiefly by observations of persons exposed to these chemicals in the course of their occupations.

With respect to the comparability of cancer as produced in animals and in man, most of the known chemical causes of cancer in man are also known to produce cancer in animals. There are at least two exceptions—arsenic and chromate compounds—which are considered to be cancer-producing in man but have not been shown to be in animals. So we cannot definitely exclude the possibility that a chemical, even though it may be negative in animals, may still be a carcinogenic chemical in humans.

Mr. WILLIAMS. Is the converse of that true, doctor?

Dr. LEVIN. The converse of that probably is also true, yes, Mr. Chairman.

Mr. WILLIAMS. But it does not follow that a chemical that will produce cancer in animals will produce it also in man?

Dr. LEVIN. Not necessarily, no.

Obviously, that cannot be as thoroughly tested as the effect of suspected human carcinogens in animals.

Mr. HALE. Is cancer as common in animals as it is in human beings?

Dr. LEVIN. That varies with the species, the strain, and the circumstances.

There are some animal strains in which almost 90 to 100 percent of the animals will come down with some form of cancer. They have been bred for that purpose. There are other animal strains in which very few will come down with cancer.

Mr. HALE. I am not talking about laboratory mice and guinea pigs, and so on. I am talking about lions, tigers, elephants, giraffes, and beasts of the jungle and the field.

Dr. LEVIN. I do not think we know enough about the natural history of such animals, most of which do not live out their full life span to the same extent as man, to answer that question.

Probably the most important animal would be the dog, which does have a great number of the forms of malignant tumors that man does.

I do not have the data on the quantitative effect. The dog does have many of the tumors which man has.

Mr. HALE. I will put it this way: Take a place like the zoo out here. Do they lose a lot of animals through cancer?

Dr. LEVIN. As far as I know, they do not. There has been some study of this question, but I do not think it has been studied as thoroughly as has cancer in man.

Mr. NEAL. Does the domestication of animals in any way increase their potential toward development of cancer?

Dr. LEVIN. I do not know the answer to that question.

I should like now to consider the chief point which I was asked to discuss, that is, methods of studying a suspected relationship between various agents and the appearance of cancer in man.

In general, there are four such methods which can be used, or which have been used. Where we suspect that a given agent produces a certain type of cancer, or where we desire to study that particular form of cancer with respect to the possibility that there are unknown agents causing it, the most usual method is what is known as the case and control method; that is, one takes a representative sample of known cases and studies the extent to which these cases have been exposed or give a history of having been exposed to the agent which we suspect. And one then compares the extent of this exposure with what is known as a control group, which may be roughly defined as a group of persons as alike as possible to the cases except for the absence of the disease.

The other method which may be used is to start with a group of persons known to be exposed to a particular chemical or agent and compare the subsequent occurrence of cancer in this group with another group in which we know that the exposure has not occurred, or has occurred to a lesser extent.

These two methods are sometimes called the retrospective method and the prospective method, because in the second or prospective method one has to wait for cancer to occur, whereas in the retrospective method we start with individuals who already have cancer. Both methods, however, are retrospective with respect to exposure to the agent we are studying.

Since the latent or "incubation" period from the time a chemical agent is first applied to the human being until the time that cancer

occurs may be 10 years or more, one may have to wait a number of years in order to obtain sufficient information from the prospective method.

In both these methods, as applied to food additives, one of the chief difficulties is that of obtaining reliable information as to exposure to a food additive. We know that good information regarding dietary habits in general is difficult to obtain. If one has to add to that very precise information as to whether the food one has eaten during the past did or did not contain a certain chemical, the difficulties would obviously be increased.

Therefore, there is considerable doubt as to whether these two methods could be used in this particular context.

The third method, and probably more practicable in this connection, is the study of special populations. By special populations, for example, I mean such a population as that engaged in the manufacture of a particular chemical. Presumably, such a population would be exposed to that chemical to a greater extent than would the general population.

A good deal of what we know about chemical causes of cancer in man has been learned by studies of such populations.

The fourth method might be termed the general population method. It would comprise, for example, the mortality or morbidity statistics of a country, State, or subdivision of a State in which there was reason to believe that there was a difference in exposure to a particular agent in other countries, States, or in other sections of the State.

For example, if there were significant differences in the application of food additive restrictions between the United States and Canada, one might expect by a study of the vital statistics of cancer of these two countries to at least obtain a clue as to whether there has been any significant difference in cancer incidence or mortality. This, obviously, would be merely suggestive that these differences may have resulted from differences in exposure to food additives and would require further study to reach any firm conclusion.

I think one of the things which ought to be pointed out, especially with respect to the third method of study of cancer referred to, is the need for special study.

In other words, one could not always rely on ordinary observation of sickness records to determine whether or not the suspected relationships exist. One must also take into consideration the fact that there is a normal incidence of cancer in all these populations.

One must not confuse the normal incidence of cancer with the incidence which is attributed to the agent studied. Also, it is quite possible that without a special study of a given population, an increased incidence of a particular type of cancer of 2 or 3 times that of the general population, might be missed.

Now, with respect to general population methods of study, it is of interest that in the last 15 years there have been reported increases in certain forms of cancer, particularly of the lung, larynx, pancreas, skin, and leukemia.

Part of these increases may be due to differences in diagnostic accuracy over the past 10 or 15 years. But we cannot be sure that this accounts entirely for these differences.

Such observations in the general population would lead us to be suspicious of the possibility that there are some as yet unknown agents operating to produce increased incidence.

The general point which I wish to make in connection with these observations is that although obviously our first line of defense in studying the possible carcinogenic effect of such substances as food additives should be animal experimentation, we should not rely exclusively on animal experimentation for the possible discovery of such effects.

There should also be systematic provision for the study of the human population, and this study should be made a part of the general control mechanism.

Dr. DARBY. Thank you, Dr. Levin.

I judge this last point that you made applies, or is particularly pertinent to, one of the general principles stated in the brochure, Principles and Procedures of Evaluating Safety of Intentional Chemical Additive in the Food, by the food protection committee, which says:

Additives should be subject to continuing observations for possible deleterious effects under prolonged and varying conditions of use and should be reappraised whenever indicated by advances in knowledge.

I think we should open the discussion on the points which have been made thus far by the speakers pertaining to the evaluation of safety.

Are there any questions from the committee or the panel?

Mr. HALE. Assume that some particular chemical is carcinogenic in its effect. And this may be a foolish question; but you will see what I am trying to get at.

Would taking one dose of the chemical so to speak be likely to produce cancer? Or would the effect be produced only by eating this food over a period of time?

Dr. DARBY. Would you like to comment on that briefly, Dr. Levin?

Dr. LEVIN. I would say for the most part that the answer would be that one dose would be insufficient. I cannot think of a possible food additive in which one dose would be sufficient.

It is conceivable, for instance, that one would ingest or inhale a radioactive substance which would then remain in the body indefinitely, and thus would exert its effect continuously and ultimately produce cancer. But for an ordinary chemical in the amounts likely to be found in food I cannot think of any chemical for which an ordinary single dose would be sufficient to produce cancer in man.

Mr. HALE. In other words, whatever the cause of cancer is, it is to be presumed that you have to have an exposure over a period of time to produce the results? Is that a fair statement?

Dr. LEVIN. In animals a single dose of a carcinogen may produce cancer, after a variable period. Presumably this is possible in man; however, for the most part known cases of chemically induced cancer in man have resulted from continued exposure.

Dr. DARBY. I think, Mr. Hale, sir, that we will have a much fuller discussion of this and other points related to cancer during the next period.

Mr. HALE. All right.

Dr. DARBY. If we can leave most of the discussion of cancer to the other speakers, there will be, shall I say, a broader presentation of this subject of cancer.

Do any members of the panel have any comments they would like to make?

Dr. FOULGER. There are one or two points I would like to suggest that may require further elaboration.

In the procedure of animal testing, we conduct a lifetime test. That is, we feed the animal every day, as a certain proportion of its total diet, the chemical under test. But in the actual life of a human eating food that does not happen.

There is a change from time to time in the fashion of using different additives. Moreover, one does not necessarily eat day after day after day the same foods, and, therefore, one does not, like the animal, take in day after day after day the same additives.

So that you see the test on our animal is a much, much, much more drastic test than that to which the humans would be exposed in the use of that same additive.

Therefore, the results of that test have a very great probative value. In addition, in this field, we must remember that we are no longer dealing with those materials—insecticides, pesticides—which are used for the specific purpose of killing organism. And the type of compounds which will be used in this field, food additives, are the types of compounds which might come, incidentally, into contact with food, in the wrapping of food.

They do not even from the start have the potentiality of the insecticide or the herbicide, which comes under the Miller amendment. While we are applying the same type of tests as we would to those, the end result of that test has a far greater value of protecting the people.

This testings has gone on for years, as all of us tried to point out to you yesterday. It has gone on voluntarily. And apart from any specific legislation on the matter, there have been two outstanding instances in which industrial laboratories found out that materials which had been used over years without any indication here or abroad of injury to man were harmful. I refer to the case of agene, a nitrogen chloride compound used to produce a particular property of flour, which was found accidentally by Melanby, in England, when the food made from that flour was fed as a high proportion of the diet to dogs, and was found to produce convulsions, or running fits, in puppies.

Despite the fact that no record of such a thing had occurred in humans, despite the fact that the compound actually causing those running fits was synthesized and was given to man in this country without producing any effects, the industries voluntarily withdrew that process from the market and so informed the Food and Drug Administration.

Not many years ago, industrial laboratories of the type that Dr. Murer and I and others have described found coumarin, a synthetic flavor simulating vanilla to be hazardous. Although it had been used for many, many years—I think I might be right in saying almost 75 years—it was not as safe as we thought it was. The industries concerned at once went to the Food and Drug Administration and explained the matter and said we are no longer going to sell this product for food purposes. So, there is a continual policing under this voluntary system by industrial laboratories investigating the hazards.

We are continually policing this whole field, apart from anything that may come under the statutory requirements of any Food and Drug Act or amendment to that act.

I think those things are interesting because it does show that we are not just waiting until we are forced to do something.

Mr. O'HARA. Dr. Foulger, while I address the question to you, of course it refers to the entire panel.

Do you feel that there is need of some legislation on this subject? There are several bills before the committee. I presume you are in a general way familiar with those bills.

Do you feel that there is some need of further legislation in the field of food additives?

Dr. FOULGER. Sir, I feel that that we have been doing things voluntarily for many, many years, that is, pretesting according to the latest methods of testing, and according to methods which keep in line with our ultimate object, the finding that the material may be hazardous to man, and I feel that that voluntary effort should be made mandatory, that we should do our testing, and that we should give that information in whole to the Food and Drug Administration, as we have been doing.

I do know something of these bills. But this is a scientific panel not concerned with legislation. And beyond that point of the simple testing and giving the data to the Food and Drug Administration, we get into a peculiar field which I think we do not want to enter into in this morning's panel.

But I, as a man who has been doing this for years, say there must be that legislation.

In science there is a principle of scientific economy: the simplest theory to explain the facts, or the simplest procedure to arrive at a given result, is the best.

I would suggest that in law there should be the same—the simplest law to arrive at the facts is the best.

Mr. LOSER. I didn't understand that last statement, Doctor.

Dr. FOULGER. In science, sir, there is a principle that the simplest theory to explain facts or the simplest procedure to arrive at an end result is the best. And, as a scientists, I wonder whether or not that does not apply to law. The simplest law which will arrive at the protection of the people in this field or any other field is the best.

Mr. LOSER. Who do you represent?

Dr. FOULGER. I represent myself, sir, as a scientist on this panel.

Mr. DOLLINGER. I am interested in your speciality. You and some of the other members of the panel are with certain companies that do research for the company in order to ascertain whether the food should be manufactured by the company? Is that correct?

Dr. FOULGER. Yes, sir.

Mr. DOLLINGER. How much independence or how much leeway or how much latitude do you have to make the determination of whether that food shall or shall not be used?

What I am driving at, Doctor, is this: suppose you and your research panel indicate or find that there is some question as to the advisability of the use of an additive. And suppose the sales department or some of the other people want to sell the item because the company may have invested money in its manufacture. Suppose they differ

with your views and think it is safe enough to use. Can you overrule the front office? Or will you have to take orders from them?

Dr. FOULGER. I am in no way related to sales or manufacture. I am completely independent. No one tells me what to say in public or in committee. I am there to give the company my best scientific advice.

If the situation arises that our tests say that this is too hazardous, I would say we should not sell that for this purpose.

And, further, over these years, whenever the material is one to be used in food, we have always in the first instance gone to Dr. Lehman or his predecessor, planned our tests with him, reported our tests to him at intervals, so that we can discuss possible modifications as things develop, and, finally, in the last instance, we have given him our data.

Now, we have very, very few compounds, indeed, which are used as food additives.

Mr. DOLLINGER. I am not speaking of your company alone. I am speaking in general.

Dr. FOULGER. Other people do the same thing, sir. I cannot presume to talk for all those companies, but I know that the other industries either have laboratories of their own, or they make contracts with university laboratories competent to do the work. And their procedure is the same.

Mr. DOLLINGER. Well, can you foresee a situation where you make such a report or the others make such a report and in spite of such a report the product still is used because they may want to go along with its manufacture?

Is there a possibility of that?

Dr. FOULGER. I think in our own company it is extremely doubtful whether that would occur, because I immediately call into my aid not merely other scientists, but the legal department, who points out what happens. And it is a policy of our company, as expressed by the executive committee, in those cases not to go out and do those things.

Mr. DOLLINGER. You used the words "too hazardous." Would that situation be true if it was slightly hazardous, or if there was a slight possibility that it was hazardous, remote as it might be, or if there was a slight possibility that it might in the future cause cancer? Would the company then suspend its operation in the manufacture of such a product?

Dr. FOULGER. Yes, sir.

Mr. DOLLINGER. If you made such a report and they differed with you, what could you do? Could you expose that to the public and say the company is taking a chance?

Dr. FOULGER. Our information would be given to the Food and Drug Administration. Even under present law they could seize the material or use an injunction against us to prevent us from using that in food.

Mr. DOLLINGER. Well, if you did that, isn't it possible that you might be without a job?

Dr. FOULGER. No, sir.

Mr. DOLLINGER. In the early part of the hearings, which go back a few weeks ago, we had a witness, Dr. Smith, who, from every indication that was given to us, had apparently a very good background.

And he indicated to us quite strongly that he and some other scientists lost their position because of the fact that they would not play ball with the companies that hired them or retained them.

And I am wondering how far that would go. I want to know whether you can comment on that situation.

Dr. FOULGER. I do not know the basis for Dr. Smith's statement. I only know that in my 22 years with the company, no one has told me what report to make. No one has told me what to say in public. I have never gone instructed to a committee.

I know that this question of what I should do or say came up in conversation with the head of the department under which I was placed during my first 6 months with the company, not as an accusation, but just as a conversation. And I told him that if anybody in the company ever tried to tell me what to say in public or what opinion to give on a medical matter, I would immediately resign.

Mind you, I had only been in the industry 4 or 5 months. I had been 15 years in academic work. He gulped once or twice, walked around the table and shook hands with me and said, "John, if that happens, I am on your side."

Mr. DOLLINGER. You can only speak of your company. But you can't tell us that that situation would be the same with respect to other companies?

There might be some that might not be as ethical and as high-minded as your company might be.

Dr. FOULGER. I certainly obviously cannot speak for other companies. But I have a good idea in this field of science and science related to health that that is the case in other companies.

May I go on to explain why, sir?

Mr. DOLLINGER. Yes, please.

Dr. FOULGER. Under the present law, we are talking in these sessions of amendments to the present law. Under the present law, the Secretary has powers that have not been mentioned in this subcommittee's hearings.

Under the present law, section 705 gives to the Secretary the right of publicity. And I can assure you that when occasion arises and he thinks it is in the interest of the public, he uses it.

All right, suppose in a company the sales department, or whoever else was involved, had completely ignored the advice of their scientists, what could happen?

The Food and Drug Administration would hear about it. Then all that they need to do is to write over the signature of the Commissioner or the Secretary a letter to the newspapers saying this matter has been brought to the attention of the Food and Drug Administration that the particular chemical is dangerous or has not been tested.

I know of an instance which came to my personal attention in which that happened. There was no further trade in that chemical.

Mr. DOLLINGER. One further question.

There have been instances, have there not, where foods were in use, in general use, and then were found to be cancer producing, and they had to cease to produce those foods?

How can you tell from such a situation if there was adequate pretesting in the company?

Dr. FOULGER. I do not know of any food that has been found to produce cancer.

Mr. DOLLINGER. Well, if it isn't cancer, it might have been in another situation where the person who used it would become ill.

Dr. FOULGER. I don't know of any food. I have searched the records, including the administration reports, since 1938 to find instances of injury to people and the medical records not only in this country but throughout the world to find proven instances of injury to people. I have not been able to find any.

Mr. DOLLINGER. With respect to additives used, have there been situations where they have caused cancer that subsequently they were taken out of use?

Dr. FOULGER. I know of no additive that has been suspected of causing cancer.

Mr. DOLLINGER. I thought I had read about that some time ago. I will have to refresh my recollection. But I think there is something to what I say, Doctor.

Dr. FOULGER. If you know of an instance, I would like to know of it. And I would try to explain the scientific side of it. But that is the extent of my knowledge now.

Dr. DARBY. I wonder if some of the other members of the panel might like to speak to some of these points.

Dr. Smyth.

Dr. SMYTH. I am Dr. Smyth. As I testified yesterday, I work in the interest of Union Carbide at Mellon Institute, another of the large chemical manufacturers. I have no authority in that corporation. I am an adviser there.

However, the corporation has long since decided—in fact, before I started to work there—that the results that my team obtains in toxicology are of most value to them when they are published in the scientific literature.

The only time there has been any suggestion affecting our publication was once they wanted a publication before we were ready, before we had made up our minds, and we said "No." And we won. There was no battle; it was just an inquiry and a reply.

Two or three times we have finished our toxicity work on a material not yet ready to be offered to the trade, and to reveal that Carbide was interested in that chemical at that time would have given away competitive information before they were prepared to market it. We have temporarily delayed publication in such cases.

Aside from that, I receive no instruction on what to publish or what to say publicly about my results.

There are no plans made for marketing intentional or incidental food additives until my team says we are convinced that it is safe. No marketing is done until we have in our hands the evidence we feel would comply with all laws and convince other people that it is safe.

It is inconceivable to me that Carbide would dispute our conclusions. I have had 20 years of experience with Carbide. The people now running it were very, very low in the scale when I started. They have risen up above me administratively. I know them. It just would not happen with that corporation that they could overrule the toxicologist and go ahead and sell.

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Furthermore, Carbide sells very little to the consumer. They try to keep fairly tight knowledge of what their customers are doing with their compounds. Their customers make consumer products from things Carbide ships in tank cars. We have in my experience, after a conference in an office, decided that this customer is not planning to use our product in a way which we approve of, and we feel that there is not enough margin of safety in that use, and we have refused to sell it to him in such cases.

That is my further contribution to Dr. Foulger's answer to your question.

Dr. CARTER. I would like to make a brief statement here in answer to the general problem that you have raised.

I am head of one of the largest chemistry departments in the United States. I have been there for 25 years. During that period of time, we have sent on into industry on the average of 40 or 50 doctor of philosophy scientists each. This year we sent 60.

We have a group of some 280 graduate students. My staff members have the closest of contact with industry and with industrial chemists. I can say that of these hundreds of scientists we have sent on and with which we keep close contact, whose advancement we are concerned with, whose positions we want to know about and do know about, that I have never known of a single case in all of these people where a man, a scientist, was fired for stating his honest opinion, for presenting the facts and for sticking up for those facts.

On the contrary, the chemical industry depends on the integrity of its scientists and can only exist over a continuing period of years and make a profit and serve the welfare of this country if it does pay attention to the scientific discoveries and opinions of the men hired to carry on research work, to develop new products, to advise as to how those products can be best handled in the long-range interest of the chemical industry.

I must admit that I look with some considerable reservation on a statement made to the effect that a competent chemist was fired because he insisted on stating his honest opinion about the data which he had accumulated.

Mr. DOLLINGER. We have such testimony, Doctor, from Dr. Smith.

He told us at the time that he knew of others. I wonder if you are familiar with the background of Dr. Smith. He was a graduate of the Harvard Medical School; he was connected with the Rockefeller Research Center and Sloan-Kettering.

Would you say there is no basis at all for this statement?

Dr. CARTER. I would not want to make comment on an individual specific case.

In any case, there are thousands of chemical firms in this country. Our Illinois graduates only go the better ones, of course. As a result of this, I would not want to say that this has not been the case.

I would say this: that among our competent Illinois graduates I have never known of such a case.

Mr. DOLLINGER. Unfortunately, we have only the representatives of some of the larger companies in the country who are ethical minded and would not stoop to that. There might be situations where other companies who have no representatives here would stoop to such a situation.

That is what we are trying to protect the public against.

I think Dr. Hueper wants to comment on that, Mr. Chairman.

Mr. DIES. As I understand it, Mr. Chairman, this panel will not be here any longer than today.

Mr. DOLLINGER. I don't want to take up any unnecessary time with the committee, but I think it is an important matter.

Mr. DIES. There isn't anything we can do about that. They have got a lot more information to give us on the general subject.

Mr. DOLLINGER. Dr. Hueper got up on his own. If he wants to comment, I think we should give him an opportunity.

Mr. WILLIAMS. It is possible we may be able to meet this afternoon. But, as I understood it, the purpose of this panel was to discuss the scientific aspect of this problem. And I think it might be well for us to proceed and go ahead with another phase of the scientific problems. Then later if we have time left possibly we can get around to other aspects.

The CHAIRMAN. I would like to make a statement off the record.

(Discussion off the record.)

Dr. DARBY. I think, Mr. Williams, that it might be well for us rather rigidly to restrict the discussion of this and subsequent presentations to matters pertaining specifically to the scientific aspects and to leave out of our discussions, if we might, or sidestep, certain questions or matters which pertain specifically to legislation, some of which we have already gotten into this record this morning, and those matters which pertain to personal relationships between companies and their employees.

Mr. WILLIAMS. Doctor, may I make an observation for the benefit of Mr. Dollinger and others?

We have this panel here at a great deal of trouble on their part and a great deal of inconvenience. They are here for the purpose of giving us a scientific analysis of the problem.

I am quite sure that Dr. Hueper, who is here in Washington, and others who may have indicated that they have problems similar to his and Dr. Smith's problem that was brought up earlier, would probably be willing to come back before the committee at a later date to pursue this particular aspect of this subject.

I am inclined to feel that the best thing that the committee could do this morning is to proceed along the lines that we had already begun and get as much of the scientific information as we can. I can assure you, gentlemen, that there is no feeling on the part of the chairman, and I am sure the members of the committee, to suppress any information that might be available.

Dr. DARBY. May I ask if there is further discussion on the points concerning safety before we proceed?

Mr. WILLIAMS. I want to ask one question.

This would be directed to the panel. I don't know whether this is a pertinent question or not. I feel like Mr. Hale did a moment ago—it may be a foolish question. But has it been shown that two chemicals, for instance, which are not carcinogenic in themselves, when placed in compound may be carcinogenic, or when taken together might be carcinogenic? And is there any danger?

If so, is that another aspect or another phase of this problem that should be gone into?

Dr. DARBY. May I suggest that we come back to this question, sir, if in the discussion of carcinogenesis it is not answered?

I think it probably will be referred to by some of the speakers. If not, then we will come back to it.

Mr. WILLIAMS. All right. You go right ahead in whatever manner you deem best.

Mr. RHODES. I would like to ask of Dr. Foulger this question: You said that you knew of no case of pretesting in which an additive was found to produce cancer; is that correct?

Dr. FOULGER. No, sir. I said I knew of no case in which an additive was used in food which produced cancer.

That was the question which you asked. I was thinking of the United States. But Dr. Cannon reminds me that there was an instance in Germany many years ago in which a synthetic dyestuff called butter yellow was found to produce cancer of the liver.

But, so far as I know, butter yellow has not been used in this country. It is banned in Germany. And I think it is banned in many other countries. I know of no instance in which an additive in food has produced cancer.

Now, over the whole gamut of pretesting the food additive, there may have been some that were found in animals to produce cancer. But they have not been used in food to my knowledge.

Mr. RHODES. Thank you, Doctor.

Dr. FOULGER. It is a different phase of the same question.

Dr. DARBY. One of the points which was asked, I believe, Mr. Dollinger, by you, was why certain additives might be withdrawn which had already been approved if this did not indicate adequate pretesting.

I do not believe that it necessarily indicates inadequate pretesting. It may indicate inadequate pretesting in light of present-day knowledge, but not necessarily. I am not referring to any specific example. Pretesting may have been adequate in light of knowledge at the time it was tested. I think the reason for this is the change in our scientific knowledge, the change in our understanding of types of tests which are important.

It is this constant need for review of methods, for reconsideration, for asking ourselves whether or not a specific substance requires review in the laboratory that has led all of the agencies, all of the scientific groups considering this question, to call attention to the need for constant reappraisal and also for the need of allowing for flexibility in any regulations so that something does not get adopted and remain adopted and protected because it already is being used or allowed or permitted, or whatever terminology one might use.

Dr. HUEPER. May I make some comment?

I think several of the statements of Dr. Foulger should not go unchallenged.

I think we are eating, practically all of us, certain foods every day—that is, milk, butter, bread, coffee, and so on. So we have a lifelong exposure to certain foods. If they contain additives, they will give us an exposure to any toxic or carcinogenic agent which may be in these particular types of foods.

There is a second item which should be corrected.

We had recently in the National Cancer Institute occasion to study the butter yellow question as far as hazards are concerned, because some

of our governmental agencies are using butter yellow for certain purposes, entailing intense human exposure to butter yellow.

There is no evidence in the entire literature, no reliable evidence, that butter yellow exposure to man ever has caused a cancer. That has been suspected. That has been claimed. We know that from experimental animals butter yellow causes cancer of the liver. We have not a single reliable valid case of cancer in human beings attributable to exposure to butter yellow for any reason whatsoever—occupational, dietary, or whatever it is.

Dr. DARBY. Are there any further questions?

Mr. WILLIAMS. You may proceed, Dr. Darby.

Dr. DARBY. If there are no further comments or questions, we shall proceed. I shall ask Dr. Cannon to reintroduce the subject of carcinogenesis.

STATEMENT OF DR. PAUL R. CANNON, CHAIRMAN, DEPARTMENT OF PATHOLOGY, UNIVERSITY OF CHICAGO, CHICAGO, ILL.

Dr. CANNON. Members of the subcommittee, Mr. Chairman, for the next half hour or so, three of us would like to review with you some of the problems in emphasizing the complexity of the cancer problem in man with particular reference to its possible relationship to chemical additives.

In other words, the problem of dietary carcinogenesis is the subject that will be discussed.

Dr. Levin has given you a very good picture of the difficulties in evaluating the cancer problem in man. I would like to emphasize in particular his fourth category, viz.:

The formulation of conclusions from the evidence for morbidity and and mortality statistics. That is particularly emphasized in relation to problems of chemical carcinogenesis. I would remind you of the fact that 25 years ago we would not have been aware of any of these aspects of the problem, because it was not until about 1930 that the chemists began to analyze various materials and give evidence of the variety of carcinogenic chemical agents present.

It has been mentioned already that there are several hundred of these. Probably more are being produced under natural conditions or artificially. So we have to think in terms of an increasing complexity in the cancer problem.

Now, with respect to evaluation of this problem in man, all we can do is to depend upon evidence from medical analysis. Diagnostic facilities are improving. Medical knowledge is increasing. But there is one handicap that has been with us and will be with us for many years. That is the small number of persons dying in this or any other country who are subject to post mortem analysis after death with microscopical examination by competent pathologists to determine the presence of cancer and the type.

I doubt that 5 percent of individuals in this country are subjected to autopsy examination after death, although in our cities, in our better hospitals, the percentage of permission autopsies runs as high as 80 percent.

Obviously with our automobiles and airplanes, when something happens to them, if 90 percent of them are thrown away without any

examination, we would not make much progress in aviation or automotive know-how.

We have to recognize this. If everyone here will try to think back in his own family, his uncles and aunts and grandparents, and try to think how many of them were subjected to post-mortem examination to get a precise diagnosis that would go into the vital statistics, you can realize our handicap in this evaluation of evidence.

Now, most of you on this committee, I presume, are trained in law; you are trained in the evaluation of evidence. You know that evidence may be biased. It may be incomplete.

We are in a realm of incomplete evidence. It is evidence we have to get. It is evidence that has been accumulating over a period of about 25 years during much of which time we have been in major world convulsions—depressions and wars—with all the handicaps to the study of this subject.

We cannot expect an early solution or an early answer to many of these problems.

I think we would be fooling ourselves if we thought we could arrive at an easy solution.

As a member of the Food Protection Committee of the National Research Council, I was asked 2 years ago to organize a small committee to start an investigation of this problem of dietary carcinogenesis, because people were starting to become fearful of carcinogenic materials in foodstuffs.

Contrary to what Dr. Foulger said yesterday, I think that that is a good thing.

I think people should be fearful of cancer. After all, in our hospitals today half the deaths are due to cancer. Our fears should be controlled, but we should be fearful. We should be aware of the hazards of our environment.

Now, on this committee, I asked Dr. Hueper here to serve and Dr. Harold Stewart, a well-known pathologist and student of the problem of cancer, at the Public Health Institute.

We made an attempt to gather the evidence as to the possible hazards from chemical additives in foods, whether intentionally or unintentionally there.

After a year or more of study, we formulated a report, and transmitted that to the Food Protection Committee, with the recommendation that a more permanent committee be established to look into this matter further.

We do not want to find out 25 years from now that there are items in our food supply that are potentially hazardous, because with many of these materials the so-called latent production time from the ingestion of the material may be from 10 to 20 years.

We know, for example, in the late twenties, when radium water was used erroneously for the treatment of arthritis in some patients, that today, some 30 years later, some of those patients are developing malignant tumors of bone from the effects of ingestion of radium at that time.

We also know where radium has been ingested for the treatment of certain morbid conditions, 25 or 30 years later bone carcinoma is developing.

It takes a long time to get facts of that sort. We don't have many of them. We are in no position to formulate any particular doctrines. We are still in a program of review.

This committee is now acting under the chairmanship of Dr. Carter. The total committee has been extended to include a wider range of experts in the field of experimental cancer.

Our problem is the collection of evidence and the evaluation of the evidence.

As pointed out as to the difficulties in the evaluation of evidence from human material, the difficulties will be with us for many years. I am sure Dr. Hueper will point out to you—and Dr. Day, also—many of the difficulties in evaluation of the experimental evidence.

I might point out, however, that it would be very simple to say you could do something about this, you could find out if there are any of these carcinogenic agents in our food. Incidentally, as Dr. Foulger said, we have not any evidence, we have only the concern now about the presence of these in the foods in this country.

But we will look for that evidence and we hope in the course of years we may find it.

Very few persons are qualified in this country to study this problem. It is a type of work that is time consuming—it is costly, and not particularly interesting to the persons doing it. So that we have at the present time to depend almost exclusively upon governmental agencies, particularly the Food and Drug Administration, which is doing very fine work in this field, but handicapped by the enormity of the problem.

If enough individuals could become interested in this as one aspect of the problem of the prevention of cancer, rather than cancer after it has developed, and has become incurable, and spend all of the time in trying to develop better drugs to cure cancer, or better therapies, I think that this sort of an investigation will be of greater value than just the examination of the problem of dietary carcinogenesis. Our feeling is that we should get fearful enough of cancer to treat it the way we treat the problem of heart disease, the way the infantile paralysist treats the problem of poliomyelitis, etc.

If everyone would get interested in helping to find out how cancer starts, what causes cancer, we could prevent much cancer—we could come out in the end much better than trying to treat cancer after it has developed. This is a problem that affects 1 out of every 4 persons, particularly in this day when we have the increase in the age in population with more people growing into the so-called cancer age, at least, an age where cancer becomes more evident.

That is the objective of our committee, of our effort in trying to get at this problem.

Our main purpose now is to emphasize the complexity of the problem. We cannot expect a simple answer of a quick solution.

Dr. DARBY. Thank you.

Dr. Hueper, would you like to continue the discussion?

STATEMENT OF DR. W. C. HUEPER, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.

Dr. HUEPER. I am Dr. Hueper. I am the Chief of the Environmental Cancer Section of the National Cancer Institute.

I have had a good inside view into the subject, not only in the general environmental and experimental aspect of cancer and the causes of human cancer, but, also, in those particular aspects which apply to the employees of the Federal Government who are in the possible area of carcinogenic operation.

The problem of actual and potential cancer hazards from chemical food additives and contaminants is directly related to the fact that an appreciable number of chemicals have been shown to cause cancer in man beyond any doubt.

Among the many thousands of deaths from occupational cancers, those are of special interest which were produced by chemicals related to food additives. For instance, about 1,500 cases of bladder cancer have been recorded as due to occupational contact with certain aromatic amines, which are used as intermediates in the production of rubber antioxydants and dyes. Of this total number of 1,500 occupational cancer of the bladder, around 400 have occurred among American workers.

The cancer-producing power of one of these chemicals, beta-naphthylamine, is so high that a daily exposure to a few micrograms for several months may result in the development of cancer in some exposed workers some 15 to 20 years later and that when a prolonged exposure to this dye intermediate occurs from 50 to 100 percent of the exposed workers ultimately will develop cancers of the bladder.

From a dietary viewpoint, it is important that several of our certified food dyes contain this chemical as one of the constituents of the multitude. I will come back to that a little later.

The high hazard factor rate of these chemicals is illustrated by the fact that the chemical industry in England, Germany, and Switzerland, and a few chemical manufacturers in this country, but not all, have discontinued producing beta-naphthylamine, because we cannot control the hazard by technologic methods.

Among the known chemicals causing cancer in man under proper conditions of exposure are benzol, naphthylamines, benzidine, 4-aminodiphenyl, various high or medium boiling derivatives of petroleum, shale oil, lignite oil, synthetic coal oils, carbon blacks, soot, coal tar, creosote oil, constituents of the crude isopropyl alcohol, arsenicals, certain chromium and nickel compounds, asbestos, radioactive substances, X-radiation, ultraviolet radiation. These are established carcinogens.

Then we have a number of suspected carcinogens—human carcinogens that are cancer-producing agents, for which we have experimental evidence and some suggestive human evidence.

In this group we have beryllium, mustard gas, and estrogens. And then finally, we have a very large list of chemicals which are used in our modern economy which enter consumer goods, including foodstuffs, for which we have only evidence from experimental animals, but for all of which evidence as to human cancer hazard is absent at the present time.

As I say, in addition to the chemicals for which conclusive or suggestive evidence exists that they can or may cause cancer in man, numerous other chemicals are used in the human economy and are incorporated in consumer goods, including foodstuffs, which are cap-

able of producing cancer in experimental animals under proper exposure or conditions. No evidence, however, at present exists that they may elicit cancerous reactions in man, although they are suspected in this respect. It is likely that at least some of them actually will be found to be actual human carcinogens.

Now I would like to define for you what is a carcinogen, because that is important. A carcinogen is a substance which under certain conditions when applied to man or to experimental animals will produce cancer which otherwise will not have occurred. It is a rather broad definition. It is perhaps the best definition we have at the present time. I doubt that it will be the final definition.

Among the food additives and contaminants which enter our food supply (and I am talking about the food supply in the United States—the problem is very much larger if we discuss it on a global scale)—there are first among the dyes three triphenylmethane dyes which when injected into the subcutaneous tissues of rats, will produce cancers. These are light green SF, brilliant blue, and fast green.

Until quite recently there was another dye which was an alpha-naphthylamine derivative, which goes under the name of orange No. 2. This when fed to rats, produces cancer of the intestine.

Then there is a third group of dyes, derivatives of betanaphthylamine (yellow AB and yellow OB), for which we have evidence when these dyes are fed to dogs that the dyes apparently disintegrate, that is, are apparently split in the organism of the dog, with the release of betanaphthylamine, because the urine of such dogs gives a color reaction considered characteristic for 2-amino-1-naphthol, which is the urinary metabolite of betanaphthylamine in dogs and man.

We cannot produce a cancer of the bladder with betanaphthylamine in rats or rabbits or mice. That is very important from the testing viewpoint.

I wish to emphasize here that the presence of these dyes in food supplies does not prove that they are cancer producing. This material has to be there in active form. The exposure to these materials, if they should produce cancer in human beings, has to take place over very long periods of time.

Among the potential human carcinogens which go into our food supply, we also have to mention estrogenic chemicals which are used for the fattening of poultry and livestock. Certain chlorinated hydrocarbon pesticide residues, particularly Aramite, are carcinogenic and contaminate foodstuffs.

Then we recently have had to face the fact that some of the radioactive materials will get into our food supply. The Food and Drug Administration has recently demonstrated that strontium has been demonstrated in milk.

We have evidence from our own observations that in industrial wastes, apparently, entering our waters, carcinogenic materials can be isolated and can produce cancer of the skin of mice when applied over a long period of time.

They may enter our drinking water supplies, although we have not succeeded so far in producing any cancer with water contaminated with industrial waste, but filtered subsequently for human consumption.

The potential hazard of these carcinogenic additives and contaminants, so far as the human population is concerned, come from three aspects.

First of all, exposure to many of these agents is lifelong. Even if we have become exposed to only relatively minute amounts. To give an illustration, the average consumption of synthetic dyes in food for the average American per year is only 4 grams. That is not very high. But we get exposure for practically our entire lifetime. Since the effect of carcinogens on the tissues are summation effects, one effect is superimposed upon the other. Because carcinogenic effects are irreversible, this aspect deserves serious consideration.

Then finally we have, also to consider the fact that materials which may be carcinogens and added to our food supply are present in other products of human consumption, or encountered in occupational activities or are pollutants of our general environment like the air, the soil, or the water.

So if one is to determine the degree of hazard which may come from food additives, one has to determine it in the light of all of the additional opportunities and intensities of exposure to the same or similar carcinogens.

From the considerations I do not believe that one can establish a safe dose of carcinogens. I do not think that we have the method or evidence available by which whe can reliably determine a safe dose. In fact, we have no safe dose of any environmental carcinogen, including radio active substances. You probably know or you remember that the so-called maximum permissible dose of radioactive exposure has been lowered in recent years several times. So we are still in the twilight area in which we do not know exactly when and where a safe dose for an environmental carcinogn may be placed.

I believe from the total evidence we have on environmental carcinogenic agents, including those of potential qualities—and most of our agents which go into foods are only potential agents—that we would be wise as a precautionary measure to exclude as far as that is practicable any addition of carcinogenic chemicals to our food supply.

I have made mention here of recent experiences which were made in Germany with arsenical pesticides. They used them freely since 1923 and up to 1942 in their vineyards.

In 1938 they discovered that the vineyard workers in the Moselle Valley had an epidemic of chronic arsenic poisoning. During the years from 1940 to now there was an increasing number of arsenic cancers of the skin observed among these workers, because they ingested rather large amounts of wine contaminated with large amounts of arsenical insecticides. Now they have among their vineyard workers not only skin cancer but lung cancer and liver cancers.

I am sure that we have to use additives, but I think we should use them sensibly. And for that reason I suppose that it would be a wise precautionary measure not to add any chemicals to our food supply which produce cancer either in man or in experimental animals.

Dr. DARBY. Thank you very much, Dr. Hueper.

Dr. Day, would you like to proceed?

STATEMENT OF DR. EMERSON DAY, CHIEF, DIVISION OF PREVENTIVE MEDICINE, SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, NEW YORK, N. Y.

Dr. DAY. Members of the committee, and members of the panel, I am Dr. Day, chief of the division of preventive medicine at Sloan-Kettering Institute, and head of the department of preventive medicine at Memorial Center, New York. I hold a professorship at Cornell University Medical College.

For the past 10 years my major activities have been devoted to the handling of two large cancer-detection centers and to the application of the principles of preventive medicine to the field of neoplastic disease.

One of the methods which we use in the program of preventive medicine at the Sloan-Kettering Institute is that of the application of epidemiologic methods in an effort to determine the causes of cancer, and thereby obtain methods for the prevention of this disease in man.

Dr. Levin has done a very able job of reviewing for you the various techniques that can be applied in the difficult field of determining causes of cancer in man. I will not spend time on that except to refer briefly to our conviction that when all of the facts are in, and this is many, many years off, I am sure we believe that there will be a determinable set of causes which underlie the various forms of cancer in man. This gives encouragement that when that day comes we can do something about controlling this disease.

I certainly agree with Dr. Cannon that the ideal is prevention of cancer, because there is obvious discouragement in our attempt to treat the disease once well established.

I would also say, in passing, that we believe there has been substantial progress made along these lines in certain forms of cancer already. I would list cancer of the uterus in women, cancer of the intestinal tract, skin and bladder cancer, leukemia, and some isolated instances of cancer of the bone. There are others which likewise are becoming better understood and therefore will be better controlled. However, there is still much discouragement and difficulty in this work.

I would refer briefly to a basic pattern which we feel is necessary if we are to talk about cancer in man and emphasize an essential requirement for research in human cancer.

To determine causes of cancer in man and bring about control we believe that the data which are to be studied must originate in man. And I would agree with Dr. Levin that there must be a continuing effort to improve our methods of learning about the natural course and the possible factors controlling cancer in man. There are a number of instances where very helpful work has started with that kind of epidemiologic data such as Dr. Levin outlined. We then proceed into the laboratory animal experimental work as an adjunct or tool to help identify possible activators or methods of action in the production of cancer, but never believe that the demonstration of carcinogenicity of the substance in animals proves that it is a carcinogen to man.

I believe that is a trap that you must not enter into. All of the animal work in the world, from my point of view, does not help us understand or control cancer in man unless there are counterparts in man's experience.

Finally, to prove the role in man, I believe we must come back from your investigation of active agents, modify them or remove them from man's environment, and then over a period of years see a reduction in that form of cancer. At that point I think one might be able to say, "this is the cause," or "that is the cause" of cancer in man, but even then one might conceivably be dealing with the unknown.

Anything short of this I would feel is inadequate to prove the cause of cancer in man.

Dr. Hueper cited a number of examples which I think are perfectly valid that have been demonstrated as carcinogenic for man. In most instances these relate to relatively small experiences with individual groups. No one doubts the validity of the demonstration of certain carcinogenic substances in soot and some of the petroleum products. And no one doubts the well-documented story of bladder cancer in dyeworkers.

On the other hand, I would feel that this, while demonstrating an aspect of cancer in man, is a very small part of the problem that we are concerned with now—the total general population exposure and hazard.

I would like to stress the evidence that animal work is not enough to take action in regard to man. There are substances—the best example may be one of the simpler things, such as glucose which, when injected under the skin of certain animals, will produce sarcoma, a form of neoplastic disease.

I do not think any one of us would be willing to say, because of that evidence in the laboratory, "This is a hazard for man." There are a number of reasons why the evidence for cancer in man is tremendously complicated when we are dealing with food additives in the general population. The problem of unknowns in what we eat, variability in the dose, or level of exposure are prime examples. This is evidenced by the need for long-term exposure before the development of tumors even with those few chemicals that are known to be producers of cancer in man.

I would think it would be a matter of 20 to 30 years for the usual cancer response in connection with established carcinogens of the type that one could expect in daily life.

I refer now to the experience in our studies of factors that may relate cancer to tobacco products. It is rare to see cancer related to tobacco, in anyone whose history of exposure is less than a period of 20 years. The average in our studies is in the mid-thirties. That is, the number of years of exposure is upward of 30 to 40 years before the sequence in this type of cancer is a factor.

I know of no field we are attacking where we are faced with more complexity or discouragement in coming up with substantial human data.

I also know now of no cancer in the general population which, after adequate study, has been suspected of being related to a food additive.

An aspect of this work which concerns me greatly has to do with the impact on the public of premature or misleading information.

Following the meeting of the International Union Against Cancer last year in Rome, there were some releases which I think everyone agrees were unfortunate but still reached the public, referring to the fact that paraffin had been demonstrated as a carcinogen. This again

was based on animal work. It was unfortunate because the word paraffin means different things to different people. But we received queries and calls from as far as the west coast from mothers concerned whether they should continue to purchase milk in wax-lined containers for their children.

This is a public responsibility which we must measure up to. And that type of event must be avoided.

I would say it is as important to prevent alarm of that sort as it is to prevent misleading information with regard to cancer cures or cancer treatment. It is in the public interest that this type of alarm be avoided.

I would feel that our objective, which is mutual on the part of scientists and legislators, must be to assure a sound approach to this complicated problem of straight toxicity as discussed in the acute and subacute aspects yesterday. In this complicated long-term subtle type of possible cancer hazard we must attempt to achieve a practical middle road, and steer somewhere between the allowance of obvious hazard, if and when there is information suggesting that this is present, and needless fear, based on misleading or premature information.

The techniques which are needed in this field are still short of adequate. I certainly agree with Dr. Levin that we must continue, by all methods that are available, to extend basic epidemiologic studies of population groups. Then we must use the animal experimental work as it applies as an adjunct to studies of man.

There is important use for animal experimentation in its proper place. We must consider the chemicals that are under study in terms of their use in food products and their potential use by consumers, not in abnormal doses and abnormal routes of exposure in animals. And we must, all of us, be doing everything possible to prevent the premature and misleading information to the public which brings about a panic and fear reaction rather than an intelligent approach to the problem.

Dr. DARBY. Thank you. Dr. Carter?

STATEMENT OF DR. HERBERT E. CARTER, DEPARTMENT OF CHEMISTRY AND CHEMICAL ENGINEERING, UNIVERSITY OF ILLINOIS, URBANA, ILL.

Dr. CARTER. Perhaps a word is in order as to why I am here, since I am not a pharmacologist or pathologist or an expert in cancer.

I suspect there are two reasons why I am here.

One is that I am a biochemist. And the other is that I am an optimist.

The immediate reason is that as Dr. Cannon has pointed out to you, I consented to become chairman of the subcommittee which he and the others originated. And this proves that I am an optimist, and it is partially as a representative of that subcommittee that I appear here today.

You have heard comments and discussions from 3 or 4 people this morning who are experts in the field of carcinogenics. And I do not want to go over or duplicate in the very short period of time the material which they have covered. But there are a few comments I would like to make.

The subcommittee, in considering the problem of carcinogenesis, faced, as is evident from what you have been told here this morning, what seemed to be an almost insurmountable problem. It would be ideal if it were possible to subject substance X to tests of the type Dr. Deichman, Dr. Smith, and others reported to you yesterday—which are adequate methods in ordinary matters of toxicological chemistry—and thus determine whether X is or is not carcinogenic for humans. You have heard the reasons why this is not possible in our present state of knowledge and with currently available methods.

One of the most important difficulties is the lack of an adequate basis for evaluating the dose-response relationship. Establishment of such a relationship is necessary in order to decide whether there is really a harmless dose level of a carcinogen. I would not go so far as Dr. Hueper and say unconditionally that there is no such thing as a harmless level for a carcinogen; with our present knowledge it simply is not possible to answer this question one way or the other.

When we are faced with a complex problem such as this, how can you go about to make the best of this situation? There certainly are some things that should be done, and there are some things that should not be done. One of the things that our committee considers highly important is that there be more attention paid to carcinogenesis as the result of ingestion of materials.

Many of the studies that Dr. Hueper and others have described were carried out by application to the skin or injection into the bladder or under the skin. These are not conditions with which we are primarily concerned in dietary carcinogenesis. These procedures provide information concerning potential carcinogens, and no one I am sure would in any wise recommend that a substance established to be a potential carcinogen under these circumstances ever be considered as a food additive. However, not nearly enough carefully planned and controlled experiments have been made to determine the possible carcinogenic effects of substances administered to animals by mouth. Much work must still be done in order to compare effects of oral administration with those obtained by other routes.

There certainly are some things that we should not do. One of these is to make general statements which can be misinterpreted by the lay public involving nomenclature of chemical substances. Dr. Day has cited the paraffin illustration. Paraffin, to a chemist means a definite type of noncyclic hydrocarbon and the commercial paraffin in this country is composed of such substances. However, in other countries the term "paraffin" is applied to materials containing both cyclic and noncycle hydrocarbons and the former may differ markedly in biochemical behavior from the latter. It is important that in speaking either among scientists or to the public that these distinctions be very carefully maintained so that it is not possible to draw incorrect conclusions from them.

Dr. Hueper mentioned betanaphthylamine as a constituent of dyes. This situation illustrates graphically the complexities and difficulties one faces in attempting to evaluate objectively the problem of dietary carcinogenesis. Betanaphthylamine has been clearly and certainly shown to cause cancer of the bladder in man. Does this mean that various dyes containing the betanaphthylamine group connected by chemical bonds to other groups must necessarily be carcinogenic.

The answer is emphatically no. It is commonplace for even a slight alteration in structure to change drastically the biological properties of a substance. Unfortunately each compound must be considered as an individual and evaluated independently. It would be completely unwarranted to generalize from the behavior of betanaphthylamine to that of a dye containing the betanaphthylamine group. A given dye may be absolutely harmless or it may be carcinogenic per se. This must be determined for each compound. A third possibility is that the dye is metabolized or degraded by the body with the liberation of betanaphthylamine, in which case it must be considered as a potential carcinogen. It is conceivable that certain types of dyes may be so converted but here again evidence must be obtained from actual experimental study. These considerations illustrate the nature of the problems involved in studies of carcinogenesis.

Our subcommittee is going to keep a sharp eye on the situation during the next few years. It will attempt to promote activities which might make it possible to better evaluate the question of dietary carcinogenesis and to follow developments in this area, but these are not likely to give a final solution, I think, to the problem that we face.

As a biochemist, I think you might pardon me in feeling much more optimistic that progress of a real, qualitative nature is likely to come in the application of biochemical principles in an attempt to find out what a cell does when it is "insulted" by a foreign chemical. And along these lines, in talking with my biochemical colleagues I find optimism which is a little greater than Dr. Day expressed concerning possible rate of progress.

It is possible to weigh a single tissue cell and to study antibody production by a single isolated cell. There are many ways in which it may be possible to find out how a cell reacts to the presence of a carcinogen long before the final appearance of the irreversible transformation into a cancer cell itself. And from this standpoint, I think progress is likely to come.

Certainly, I would agree wholeheartedly with Dr. Hueper that a proven carcinogen should not be included as a food additive. I would underline, however, both "proven" and "carcinogen" in this regard.

I think that during the course of the next few years we will develop better ways of evaluating potential carcinogens and that by careful study and comparison of different species of animal it may be possible to arrive at some more general statement as to the relationship of carcinogenesis in laboratory animals and in humans. That this is not now possible was the conclusion of our subcommittee which is composed of experts in a variety of different fields of cancer research.

I think we can make progress by a careful, judicious, unexcited survey of the scene, and with the pushing of every possible avenue and tool which might provide additional information beyond that which we now have available.

Since there is so little time, I think perhaps I will discontinue my remarks with this.

Dr. DARBY. Thank you.

There is considerable mention, if I might say so, of keeping out dietary carcinogens. One practical value to us in our consideration of regulatory matters, perhaps, can be expressed as avoiding the burden of requiring some unnecessary test procedures on products or on sub-

stances in which there is very little reason for doing. Particularly, as tests may often be in an indecisive, inconclusive stage that I think one realizes after the discussion this morning.

This does not mean that I feel that we should say we should not do tests, but the tests which have not been described in detail here, but which have been carried out, involve large numbers of animals over rather long periods of time. Animals are exceedingly expensive.

Yesterday, I think, someone estimated that the ordinary toxicologic test runs about $40,000 to $50,000 each on a compound. Studies on carcinogenicity will run that much and more. So that I think we can see the hopelessness of expecting that every substance which might appear in food might be subjected to a test of carcinogenicity before it is used.

Again it must be emphasized there must be an area in which judgment has to be exercised in order to decide which of these we should study, by which methods, by which routes, and so on, and which ones we may avoid studying and still feel that we are safe within the qualitative or, should I say, the quantitative connotation that we have been using in these discussions.

Mr. DOLLINGER. Dr. Darby, someone mentioned one for the fattening of fowls; do they call it estrogens?

Dr. DARBY. There are uses of estrogens.

Mr. DOLLINGER. Dr. Hueper mentioned the fact that estrogen is in use to fatten fowls.

Dr. DARBY. Dr. Hueper said that.

Mr. DOLLINGER. I was wondering in the fattening of the fowl, what their action is?

Dr. HUEPER. They are used in two forms. They are added either to the feed, the synthetic estrogen, or they are implanted into the neck of the chicken in pellet form, about 12–15 milligrams per dose.

Mr. DOLLINGER. They have definitely produced cancer in the human being; have they not?

Dr. HUEPER. I didn't say that.

Mr. DOLLINGER. I am putting words into your mouth. They do produce cancer in the fowl; do they?

Dr. HUEPER. No, no. The chickens do not live long enough.

Mr. DOLLINGER. Are there instances where the estrogens are not dissolved when they are sold?

Dr. HUEPER. Then the consumer gets a pretty stiff dose of estrogen when he gets it. For instance, if estrogen pellets are not implanted into the neck—if the farmer finds it more convenient to implant it into the muscle tissues of the chest, the consumer eats it, and he gets a good dose. That has happened.

Mr. DOLLINGER. We do not know what the effect in later life will be.

Dr. HUEPER. We do not know that.

Mr. DOLLINGER. And we permit those things to be sold?

Dr. HUEPER. I don't.

Mr. DOLLINGER. I do not mean you—they are being sold?

Dr. HUEPER. Well, they are sold. You see it is this way, if the pellet is implanted into the neck of the chicken and the head of the chicken is removed, necessarily the consumer never gets that pellet.

Mr. DOLLINGER. If I want to eat the neck of the chicken, then I am in trouble?

Dr. HUEPER. Another point, if it is kept alive for 6 weeks before it is killed, the estrogen usually has disappeared.

Mr. DOLLINGER. Do we know when the chicken is sold to the consumer that it has happened?

Dr. HUEPER. According to our market reports, we have 100 million broilers prepared with that material. To control that many chickens, I think we would have to have complicated machinery. That machinery is paid for by the taxpayer, not by the man who puts the estrogen into the chicken.

Mr. DOLLINGER. That is right.

Dr. FOULGER. I think the most outstanding effect is that mink, fed chicken necks containing stilbesterol, failed to breed.

Dr. DAY. It is important to point out there is no evidence suggesting that that type of exposure of humans to estrogen will lead to cancer.

Mr. DOLLINGER. There is nothing definite to the contrary—whether it will be effective? There is a possibility, would you not say that?

Dr. DAY. I think the exposure we are talking about is first of all fortuitous; mind you, there is no hazard so far as we know, and nobody expects hazards from the fattened meat. It has to be that the estrogen has not been absorbed by the chicken. It is inconceivable to me that this approches any kind of level which would make the medical profession feel that this is a hazard to be taken seriously.

Mr. DOLLINGER. Would you not say there is a possible hazard in this case? You could not rule it out definitely?

Dr. DAY. I would not want one of my patients to take the amount of estrogen contained in the neck of one of these chickens that has not absorbed the pellets on a weekly basis, I agree with you. Over a period of time that could be hazardous, I agree.

Mr. DOLLINGER. May I ask one other question? Anyone who represents a chemicobiologic concern, if there was such a situation in their company, would they attempt to prevent the use of it?

Dr. SPENCER. You mentioned diethylstilbesterol in animal feeds. I believe there is ample evidence showing that diethylstilbesterol as used in animal feeds and allowed by the Food and Drug Administration does not appear in meat at the time it is ready to be eaten. I believe that this fact is well established. I think there has been a lot of notoriety on some misuse of chicken necks that had diethylstilbesterol pellets in them. I think you have that information correct.

The point that Dr. Day made, I believe, is correct to the best of my knowledge.

Dr. Foulger mentioned it simply because estrogens have been used in animal feeds.

Mr. DOLLINGER. The point I raised was that if there was any evidence at all I do not think the public should be misled.

Dr. FOULGER. Pharmacologically, sir, the evidence is that the dose which remains is not adequate to lead to serious effects. If you eat the pellets there could be a disturbance of the endocrines, the balance between male and female. It would not lead to cancer, it would lead to other disturbances.

Mr. DOLLINGER. That is under the system of present methods of testing, the evidence this morning has indicated that you will not know for some years whether or not there will be the effect of producing cancer. It has happened with cancer of the bone and so forth.

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Dr. Hueper testified it takes some years for that to become effective. I think we have been taking a desperate chance in permitting such things to be used for human consumption. That is my own opinion.

Dr. FOULGER. I agree with you on that.

Dr. HUEPER. May I add one word, if I may, sir?

Mr. WILLIAMS. Yes.

Dr. HUEPER. I do not believe that any dietary use or abuse of estrogens in chickens would by itself produce cancer in human beings. I do not think that would happen. But it may represent—at least one has to consider the possibility of a contributory action of estrogen on human beings exposed to estrogen from other sources. I have here a recent instance. The newspapers brought out the news that vitamins were contaminated with estrogens. The newspaper report noted only four cases of the effects of estrogen.

There are other customers who ate these vitamin tablets contaminated with estrogens, and those customers, also, had some effect. The four cases do not reflect the scope of possible hazards that were produced.

Mr. DOLLINGER. But if there is a risk?

Dr. HUEPER. It is not an immediate risk.

Mr. DOLLINGER. I think it is a risk I would not want to assume.

Dr. DARBY. With or without pellets?

Dr. SPENCER. The amount of estrogen in animal feeds is controlled by the Food and Drug Administration under the new drug section of the act. In the case of diethylstilbesterol it has been demonstrated that diethylstilbesterol is not present in the meat prepared for human consumption.

Dr. CARTER. One other point might well be made here. This is a factor that complicates many of these considerations that we are exposed to in our diets to small amounts. Alfalfa has estrogen in it normally; milk has as much as 4 or 5 parts in dried milk of estrogen in it.

Mr. DOLLINGER. In its natural state?

Dr. CARTER. Yes; that is right.

Mr. DOLLINGER. Why look for any further trouble?

Dr. CARTER. That is right. The amount that you are considering, perhaps, in meats and some of these other things, are very much less than these amounts that are normal in some products you are already exposed to, compared to what we are getting, anyway.

Mr. DOLLINGER. I think we are trying to increase our lifetime, so let us cut out the extra ones. That is what we are trying to do. That is all.

Mr. RHODES. Do I understand that in pretesting that some tests would be excessive in cost and that it would not be practical for various reasons to have additives pretested before their use is permitted.

Dr. DARBY. I am not quite certain as to what extent you mean, sir. That some would be—that some of the bills proposed would be impractical.

Mr. RHODES. Yes; in regard to proposals for pretesting additives.

Dr. DARBY. I do not believe we have expressed ourselves on that. I think the point in my comment was that they should be examined with this point in mind. I think we have not expressed ourselves in relation to any specific bill. We have deliberately avoided that because we feel that is really a legal matter.

I expressed, and I judge that I have some people on the panel at least that are with me, that one should be careful of attempting over-optimistically to require that every substance which is used be subjected to a series of tests for carcinogenicity, because, as we have heard this morning, if you run a test in one species of animal or in two species, that may or may not have application to man. If we find positive results, I think most of us would agree that one should, certainly, be very cautious, indeed, about suggesting that this be allowed in food. But if we find negative results it may have no particular meaning. Therefore, if one required at this stage of our knowledge about testing that every substance be subjected to a long series of studies it would be an impossible and unwieldy situation.

Mr. RHODES. I would like to ask this question of any of the panel. If any additives now being used would be found unsafe would it cause serious economic loss to the chemical or food industry if discontinued.

Dr. DARBY. Would you repeat that question, please?

Mr. RHODES. If any additives which are now being used were found unsafe, would it cause serious economic loss to the food and to the chemical industry?

Dr. DARBY. Would you like to answer that?

Dr. MURER. The answer is "Yes," they would, and this has already happened in some instances. They have been removed. I think it is the normal thing that would happen.

Mr. RHODES. Dr. Foulger said that the industry operates on a high ethical level. I accept that statement, but I wonder if this would be true where great incomes could be destroyed, such as in the tobacco industry, if it was found that its products were not safe for public consumption. Do you believe that any scientist who wants to keep his job would dare to express an opinion if it were in conflict with the economic interest of the industry that employs him?

Mr. MURER. Since I can only give my opinion, I cannot speak for all in the industry. Our company, however, has a corporate policy written and signed by the chairman of the board which says that chemical additives may not be used unless they are adequately tested and demonstrated to be safe by the scientists in our laboratory. This is company policy. When we determine that a chemical is not safe to use, it is not used.

We have had the experience in our organization of finding a new use for a natural-occurring chemical. However, after testing it in our laboratory, it was our opinion that it was not adequately safe for use. We informed the manufacturers of the compound. One of them who had about 80 percent of the business with this material stopped its manufacture without evidence other than that which we obtained in our laboratory and went out of business in 24 hours.

Dr. SPENCER. Mr. Congressman, I can speak very definitely on this point, citing a specific example. A natural flavor, that has been used for about 75 years, is synthesized by the Dow Chemical Co. We felt that it was a safe material as demonstrated by long usage.

However, when new information came to our attention indicating that this material had certain toxicological properties of which we were unaware, we went before our management and presented the facts. Without hesitation our management pulled this material off the market so far as its use as a food-flavoring component is concerned.

I think that Dr. Foulger mentioned earlier this morning another example.

Dr. DEICHMANN. I would like to add another example. It does not apply to food additives but demonstrates the point previously made as to the high standards which are being maintained and practiced by many of our large industries.

I am referring to a chronic-feeding experiment which we completed about 2 years ago in our laboratories at the University of Miami. We presented experimental evidence that a certain compound produces cancer in the urinary bladder of the dog.

The company which made and sold this chemical, upon receipt of our report, announced to the whole chemical industry that it would discontinue the manufacture and the sale of this compound. They closed down the whole affair.

Mr. DINGELL. What was the amount of the business?

Dr. DEICHMANN. It was a million-dollar business to the company.

Dr. PETERS. Scientists have two great possessions. First, the desire and ability to ascertain the facts—to ferret out the truth. Second, and equally important, is the scientist's reputation for absolute honesty. There is nothing that will ruin a scientist professionally as quickly as will his departure from the truth about a scientific experiment. No industry scientist can possibly afford to speak other than the truth when he is asked for the facts. In my particular company, the law department will never O. K. any formula or technical advertising claim until it has been approved by the research department.

Mr. RHODES. I believe that may be true of food and chemicals. I wondered though if it would be true where a whole industry may be destroyed, where many people would be affected economically, if it were found that the product being used produced cancer, or was found unsafe for public consumption.

Dr. MURER. It has happened in 3 or 4 cases. This does not destroy industry, and it does not destroy companies. It destroys businesses within them and rather large and substantial ones. This is part of the game.

This has happened on 4 or 5 occasions. This is part of the game.

Mr. WILLIAMS. May I interrupt, before we respond to the call of House. At this point I would like to place in the record a copy of a letter received from the American Cancer Society under date of July 22. I shall not read the entire letter, but I would like to read the recommendations that were made by the Cancer Society:

> I would strongly urge that your committee recommend legislation to the Congress to strengthen the Food and Drug Administration, and that this legislation embrace the following principles:
>
> One, that the proponent of any proposed chemical additives be required to conduct tests which will demonstrate that the additive is safe for human consumption, and in the manner in which it is being used, and that these tests include (1) to determine whether the additive may be carcinogenic to an experimental animal.
>
> The adequacy of these tests to be determined by the Food and Drug Administration.

And the second recommendation, and I quote:

> That permission for the additive be withheld until its safety has been demonstrated to the satisfaction of the Food and Drug Administration by the proponents, and third—and this is the most important at the moment with regard to the discussion that is going on.

That no substance shall be approved if found to induce cancer in man or after tests, it is provided in No. 1—

that is the first recommendation above—

found to induce cancer in the animal.

Briefly, we do not have but about 5 minutes at the most, and I wonder if any member of the panel would like to comment on those recommendations or the third recommendation in particular?

(The letter referred to is as follows:)

AMERICAN CANCER SOCIETY, INC.,
New York, N. Y., July 22, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Health and Science Subcommittee,
Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. WILLIAMS: As chairman of the legislative committee of the American Cancer Society I am writing to tell you of the great interest we have in the various proposals for legislation which your committee is considering in connection with food additives and to give you our views on the basic problems which seem to us to be involved.

The society's fundamental concern is to find the cause of cancer, and then a cure, and ultimately the means of preventing this disease which now takes the lives of well over a quarter of a million of our citizens each year.

We are well aware that in our modern civilization there are many factors which may cause cancer in human beings. Here our interest is to eliminate these possible cancer causes, as far as this may be accomplished, as the best way of cutting down the cancer death rate.

You are doubtless aware of the work the society has done in determining the relation of smoking to the greatly increased incidence of lung cancer. Here our approach is one of education of the public so that each person may make his own decision on smoking with full information available.

Another field in which we have great and growing concern is the possible effect of chemical food additives on health, with particular reference to cancer. We know of the comprehensive study undertaken by a select committee under Congressman Delaney some years ago. In fact our then medical and scientific director, Dr. Charles S. Cameron, testified before that committee. This study has clearly demonstrated the inadequacies of present legislation.

Here the problem is one in which the individual citizen is powerless to protect his own health but must depend upon the Food and Drug Administration.

We believe that in considering the health problem created by the increasing use of chemical additives in food the adage "an ounce of prevention is worth a pound of cure" is particularly applicable.

We strongly urge that your committee recommend legislation to the Congress to strengthen the Food and Drug Administration and that this legislation embrace the following principles:

1. That the proponent of any proposed chemical additive be required to conduct tests which will demonstrate that the additive is safe for human consumption in the manner in which it will be used, and that these tests include one to determine whether the additive may be carcinogenic to experimental animals. The adequacy of these tests should be determined by the Food and Drug Administration.

2. That permission to use the additive be withheld until its safety has been demonstrated to the satisfaction of the Food and Drug Administration by the proponent.

3. That no substance shall be approved found to induce cancer in man, or after tests provided in No. 1 above, found to induce cancer in animals.

We are aware of the various proposals now pending before your committee and we have full confidence that you will approve the measure which will most effectively accomplish these purposes.

Sincerely yours,

JAMES S. ADAMS,
Chairman, Legislative Committee.

Dr. DEICHMANN. I would like to comment very briefly on this. I am a pharmacologist, I am not an expert on cancer.

I think we should be very cautious and careful before we condemn all compounds, all food additives, which might produce cancer in some animal species.

We have heard testimony here today to the effect that there are certain animal species which are highly susceptible to cancer; in fact, spontaneous cancer will occur in some of these animals to an extent of 80 percent.

I see no reason to reject a compound considered as a food additive for the sole reason that it produces skin cancer in a hypersensitive mouse.

On the other hand, we have other experimental animals: for instance, the dog. As far as I know, the dog is the only animal in which we can produce bladder cancer as we see it in man.

For this reason, I would, most certainly, condemn any compound which produces bladder cancer in the dog, regardless of its mode of administration and dose.

We must choose our experimental animals wisely before we are entitled to draw conclusions.

Dr. CANNON. We commented on the letter either yesterday or the day before. That was a letter probably expressing a personal opinion rather than a group opinion. That was our understanding of it. We took that position. It represented an opinion that probably does not appreciate many of the complex problems discussed this morning.

My own opinion about this—and I am sure that is the problem we all have to deal with in legislative problems—is that it is very easy to pass a law, but it is very difficult to know whether that law is a wise one.

And I felt that, as to this letter, they might have a convention and vote unanimous on it; that would be a different matter.

This is a matter that he is going to test these compounds when there is no one available. No one has the ability to do it.

So I think that that type of recommendation has to be taken as an opinion.

Dr. DARBY. I would think, sir, that the second statement—and I cannot repeat it—says "will include tests." If it read "may include tests as required by an agency," such as Food and Drug Administration, I think that it would be a much more reasonable appraisal of the possibilities.

I think again we must come back to some group which does make a decision that it is worth expending this effort and this portion of our natural resources—and when I speak of those I mean national scientific resources, because these are very burdensome types of study—to conduct these studies and not make it mandatory that everything be subjected to a rather large series of studies.

I might say that I was chairman of a committee which looked at the food-dye program in the Food and Drug Administration a few months ago, and we estimated that the study of the food dyes, by procedures which seemed quite reasonable procedures to propose, would consume, if I recall correctly, something like 25 years of manpower presently in Food and Drug.

I think this gives you some idea of the magnitude and the scientific task which we are setting up, if you say that every substance must be subjected to such scrutiny.

Mr. RHODES. Before we adjourn, I would like to pay a tribute to each one of the panel members for the interesting and expert testimony and opinions that they have given us.

I believe I speak for all members of the committee in saying that. I think you have made a great contribution.

Mr. WILLIAMS. I assure you that you speak for me and the other members present. In view of the fact that our time has been limited, we will be glad to keep this record open for a reasonable length of time in order to permit any panel member who might desire to do so to amplify his remarks. Of course, that is purely optional with members of the panel if they should so desire.

In closing, permit me also to express, on behalf of the committee, our deep appreciation to each of you gentlemen individually and collectively as a panel for coming before this committee and giving us this information. Only one member of this subcommittee that I know of has been trained in the field of science, and that is Dr. Neal, who is a medical doctor. This is a highly complex problem. And if there is anything that has impressed me, it is the difficulty of the task that this committee is confronted with in attempting to write legislation dealing with this subject.

I remember several years ago a former member of this committee who was sitting next to me made a remark that I thought it might be well to repeat here.

We had a scientific witness on the stand, and he had gone into a rather complex scientific problem, using scientific terminology throughout his testimony. And when he had concluded his testimony, I turned to my colleague, sitting next to me, and I asked him if he would like to comment on that testimony. He said, "If he had just put it on the lower shelf, I would not have so much trouble reaching it." [Laughter.]

I want to thank you gentlemen for keeping your discussion on a shelf low enough for the committee to reach, most of it, at least.

We are very grateful to you for the information that you have given to the committee. We wish to thank you again for your kindness.

Dr. DARBY. Mr. Williams, may I express our appreciation of the very kind attention which you have given us. Certainly if our discussion here has in any way helped in clarification of some of the questions in the minds of your subcommittee and your larger committee on legislation or regulatory matters, whatever effort we have made has been worth our effort.

I am certain that I speak for the whole panel when I tell you that it has been an exceedingly pleasant experience to sit with your subcommittee and to have the help and guidance that you people have very kindly afforded us in steering us into the type of discussion which might be of some use to you.

For the record, it should be recorded that Dr. Blackwell Smith and Dr. Maurice Seevers were unable to attend today's session. Thank you very much, indeed, sir.

Mr. WILLIAMS. The committee will stand adjourned.

(Whereupon, at 12:30 p. m., the above hearing was adjourned.)

(In accordance with the suggestion of Mr. Williams, the following additional statements were later submitted by members of the panel:)

BETHESDA, MD., *August 8, 1957.*

Mr. JOHN BELL WILLIAMS,
Member of Congress, Chairman, Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce, Washington, D. C.

DEAR MR. WILLIAMS: Because of the limited amount of time available for the deliberations of the members of the panel on toxic and carcinogenic health hazards from food additives and contaminants, I feel that I was unable to present to you and the other members of the subcommittee my thoughts on the subject of cancer hazards in an adequate fashion. You may, therefore, wish to have a copy of the notes which I had prepared for this occasion and which reflect my view on the matter more concisely than I was able to do at the hearing before you and your committee on August 7, 1957.

These notes may perhaps help in providing you and your colleagues with information which may be representative of the consumers' point of view; i. e., the many millions of Americans who will have to consume the food additives, which are or may be introduced into our foods, and who may be subjected to any damage to their health possibly resulting from such manipulations if these are not properly controlled.

Sincerely yours,

W. C. HUEPER, M. D.

Enclosure.

NOTES FOR THE SCIENTIFIC PANEL DISCUSSIONS ON CHEMICAL ADDITIVES TO BE HELD ON AUGUST 6 AND 7, 1957, BEFORE THE SUBCOMMITTEE ON HEALTH AND SCIENCE

The problem of actual and potential cancer hazards from chemical food additives and contaminants is directly related to the fact that experiences made in many industrialized countries during the past 75 years have definitely demonstrated the existence of cancer-producing chemicals of diverse but specific character. According to published records, many thousands of cancers affecting various organs and tissues have been observed among workers having contact with these chemicals for occupational reasons. For instance, several aromatic amines, i. e., alpha- and beta-naphthylamine, benzidine, and 4-aminodiphenyl, which are used in the manufacture of dyes, including several certified food dyes, and of rubber antioxidants, account for the reported occurrence of about 1,500 occupational bladder cancers among workers of American and European chemical industries. More than 400 of these cases were observed in American dye plants, while no information in this matter is available for American rubber workers, although aromatic amine cancers of the bladder have been found among English rubber workers. The actual number of these particular occupational cancers is most likely distinctly higher because of defective records. In fact, the cancer hazard from contact with beta-naphthylamine and 4-aminodiphenyl has been found to be so high and technologically noncontrollable that most of the large chemical manufacturers have discontinued in recent years the production of these two cancer-producing chemicals, which during the early days of manufacture caused the development of bladder cancer in from 50 to 100 percent of the exposed workers. An exposure to a few micrograms of beta-naphthylamine per day sustained for several months is adequate for causing bladder cancer in some individuals.

It is thus a well established fact that an appreciable and growing number of chemicals, of which a few are known to enter the human food supply, are capable of causing and do cause cancers in man under proper conditions of exposure. This disconcerting situation is aggravated by the observation that many additional chemicals, some of which are incorporated into consumer goods including foodstuffs, elicit cancers in experimental animals when introduced in proper amounts and under suitable conditions. Although at present no evidence is available that they have done so in man, they must be suspected of possessing this property, because many of the chemicals which for occupational reasons produce cancers in man have subsequently been shown to have an identical effect on experimental animals. It is, therefore, likely that at least some members of the long list of these potential human carcinogens will ultimately be shown to be actual human carcinogens. These observations and considerations indicate that an uncontrolled introduction and an indiscriminate use of chemical food additives create or may create cancer hazards to the human population.

On the basis of information available on carcinogenic properties of presently used or permitted food additives and contaminants the following chemicals must be considered carcinogens according to the widely accepted definition that carcinogens are agents which when applied under certain conditions to man or animals elicit the subsequent development of cancers which would not have appeared otherwise.

1. The triphenylmethane dyes, light green SF, brilliant blue, and fast green, and the beta-naphthylamine azo benzol dyes yellow AB and yellow OB used for coloring butter, margarine, and baked goods.

2. The preservative 8-hydroxyquinoline, which also is used in contraceptives and rectal suppositories, as a fungicide in European tobaccos.

3. The synthetic mucilage carboxymethyl cellulose.

4. Arsenicals found in foodstuffs as pesticide residue, and as an additive of animal feeds of poultry and livestock.

5. Estrogenic chemicals used for promoting fattening of poultry and livestock.

6. Chlorinated hydrocarbon pesticides, especially aramite and DDT, present as residues in foodstuffs.

7. Polycyclic aromatic hydrocarbons with carcinogenic properties contained in soot adherent to smoked goods or generated in foodstuffs by the application of excessive heat during roasting and grilling procedures.

8. Wrapping and coating materials composed of polymerized carbon and silicon compounds, such as cellophane, polyethylene, and polyvinyl chloride.

9. Paraffins and mineral oils if insufficiently refined, and employed for the coating of foodstuffs, such as cheeses and fruits, and for the impregnation of food containers.

10. Radioactive substances either attached to the surface of foodstuffs from radioactive fallouts or entering plants and animals through absorption from contaminated water and soil.

11. Polluted water: Oysters, carbon adsorbates.

Although the mere presence of these carcinogenic additives and contaminants in foodstuffs does not prove by itself that an actual cancer hazard exists for the consuming public, their presence nevertheless represents a cause of serious concern, because of the following reasons: (1) Their frequent and often lifelong introduction into the human body even in small or minute doses produces a progressive carcinogenic summation effect. (2) The irreversible nature of the cumulative individual effects may ultimately be sufficient for eliciting cancerous reactions. (3) Contact with dietary carcinogens contributes moreover to the total carcinogenic load acquired by modern man through his exposure to the same and other environmental cancer-producing agents from various sources.

The significance of such correlations while by now generally appreciated concerning cancer hazards from exposures to ionizing radiation is applicable with equal force to other carcinogenic agents, because in contrast to the reversible toxic effects of chemicals, their carcinogenic effects upon cells and tissues are largely irreversible. It should be obvious from these observations that carcinogenic chemical additives and contaminants have no place in our food supply as a matter of wise precaution.

Definite precautionary measures in this respect are indicated because cancer hazards associated with constituents of foods fulfill two of the main requirements for a successful production of cancers among consumers:

1. The exposure to such agents is usually frequent, prolonged and often lifelong and involves doses which are in general well below the minimal toxic doses. Toxic warning symptoms therefore are absent as a rule. Experimental observations indicate the possibility that contact with carcinogenic chemicals may affect the fetus during intrauterine life through penetration of these chemicals from the mother through the placental barriers to the fetus. Other findings suggest that carcinogenic exposures of infants may be sustained by carcinogens excreted with the milk of the mother.

2. A large proportion of the exposed individuals lives sufficiently long for surviving the latent period of years or decades which elapses between the first exposure to a carcinogenic chemical and the appearance of a cancer. The presumably long latent period associated with exposures to dietary carcinogens would be compensated for by the start of carcinogenic contact at an early period of life.

The observations and considerations so far presented provide adequate justification for subjecting all presently used and permitted food additives and contaminants to thorough screening procedures by experimental methods for carcinogenic properties. It has been claimed that such tests should not be required

for those chemical additives which have been in use for many years without having become suspect of having carcinogenic properties and without having caused cancers among the consuming public, and which therefore should be considered as safe. Practical experience in environmental carcinogenesis, however, shows that absence of incriminating evidence is not an adequate guaranty for the carcinogenic innocuousness of a chemical.

In fact, it is rather difficult if not impossible with the present biologic and epidemiologic methods to demonstrate conclusively cancerous effects in members of the general population attributable to any particular chemical food additive, once this substance has been put to general use. Almost all cancers caused by specific environmental agents cannot be distinguished from the large host of cancers of still unknown causation by any specific morphologic or biochemical characteristic. Moreover, cancers of the same morphology and affecting the same organ or tissue can be elicited by several of the already known cancer-producing environmental agents. Epidemiologic-statistical investigations and methods can at best discover quantitative changes in incidence rates of cancers of certain organs or tissues but do not provide any conclusive or reliable information on the specific causes underlying such fluctuations. It is probably for these reasons that in the past no serious attempt has been made at ascertaining any pertinent data on possible carcinogenic effects elicited by chemical additives used in foods without adequate carcinogenic testing to which the protection of the so-called "grandfather clause" is proposed.

The possible danger to the health of the general consumer which might and probably will result from the adoption of this clause is apparent from the following two experiences on occupational cancer hazards made during recent years, where situations prevail which are definitely less complex than those encountered in any attempt at demonstrating the effects of a dietary carcinogen on the general population exposed to a great variety of known and unknown carcinogenic factors from many sources. Several years ago a prominent biostatistician certified to the president of one large chemical company that the statistical analysis of the cancer death records of the employees of this organization showed a cancer death rate below the general standard rate and thus the absence of any occupational cancer hazard. A subsequent examination of these data submitted to me by the president a few months later revealed that the death rate from cancer of the bladder among these workers stood at 30 times the normal rate and that this phenomenon was attributable to the use and processing of specific cancer-producing aromatic amines employed in the production of dyes and known for their carcinogenic properties in industry for several decades. Epidemiologic-statistical data when incompetently obtained, analyzed, and interpreted thus can yield highly misleading information on the presence and nature of environmental cancer hazards.

Another observation made only during recent months indicates that the occurrence of occupational cancers caused by well and long-known chemical carcinogens may remain unnoticed or unreported for many years, although the circumstances favoring their discovery were most favorable. It was shown in recent studies of an officer of the health department of one of our Midwestern States that workers employed in a certain chemical plant and producing and handling a highly potent chemical carcinogen had developed bladder cancer in most instances. The plant had been in operatiton for over 30 years. The inclusion of the "grandfather clause" into a law intended for the protection of the general public against potential cancer hazards from food additives and contaminants is not justifiable on scientific grounds and is not in the public interest.

Similar scientific and practical objections may be raised against the adoption of an allegedly "safe dose" of a carcinogenic chemical food additive and contaminant. While it may be admitted that theoretically such a dose may perhaps exist and may possibly be found for experimental animals exposed to and living under well controlled experimental conditions, there is no scientifically valid and practicable method available for determining a "safe dose" of carcinogens for humans. In fact, science has failed so far to establish a "safe dose" for any of the many recognized environmental carcinogens, although knowledge of such a dose would be of utmost practical importance to industry and public health agencies.

The following additional evidence and considerations militate against the adoption of a "safe dose" for carcinogenic chemical additives and contaminants:

1. Marked specific differences in the degree of reactivity to a particular carcinogen do not permit the reliable determination of a "safe dose" of a

carcinogenic chemical additive for man based on the variable evidence obtained in experimental animals.

2. Observations made with occupational carcinogens demonstrate the presence of definite variations in the degree of susceptibility to a particular carcinogen by different individuals. The general population, moreover, is composed not only of normal individuals but also of a considerable proportion of metabolically defective and sick individuals possessing most likely varying susceptibilities to carcinogenic agents. The existing experimental methods of determining the relative carcinogenic potency of chemicals do not permit an adequate assessment of these factors which are essential for the establishment of an allegedly "safe dose" of carcinogenic chemical additives.

3. Living and exposure conditions prevailing for the general human population are not standardized and vary considerably in different localities, population groups and age groups. Results obtained in well controlled animal experiments therefore, are scarcely applicable to human conditions of exposure, related to food consumption.

4. The claim of an allegedly safe dose of a dietary carcinogen disregards completely the important fact that the entire population becomes exposed during its lifetime to an appreciable number of known and unknown carcinogenic influences which are in part identical with those carcinogens recommended for inclusion in the general food supply, and which doubtlessly may accentuate the action of dietary carcinogens. Under the existing conditions serious efforts should be made to reduce the number of carcinogens and the opportunities of contact with them so as to control cancer hazards by preventive measures and to decrease the total carcinogenic dose received by the general population. The inclusion of nonessential carcinogenic agents in any amounts in the daily diet would violate a fundamental principle of cancer control.

5. Finally, consideration should be given to the fact that the inclusion of carcinogenic additives in foodstuffs even in allegedly safe doses necessitates the institution of complicated and expensive control measures which would be paid for by the general taxpayer. Since the use of such carcinogenic chemical additives is not in the interest of the taxpayer, he should not be forced to provide funds for his own protection against hazardous and nonessential chemicals added to foods for the financial benefit of the manufacturer of the chemicals and the producers and processors of the foodstuffs.

Our present modern food economy necessitates the use of some food additives and makes the presence of some contaminants in our food unavoidable. The available information on toxic and carcinogenic health hazards which might be connected with such practices supports the view, however, that all prospective additives and contaminants be subjected to rigid tests for determining their toxic and carcinogenic properties before they are permitted to be used in foodstuffs if found acceptable. The addition of any chemicals to foodstuffs which possess carcinogenic properties when tested on animals regardless of the route and dose use should be prohibited since such additives are bound to increase the carcinogenic load of the consuming public.

The pretesting of all present and prospective food additives and contaminants for carcinogenic properties represents, in my opinion, a fundamental requirement for an adequate protection of the public against environmental cancer hazards. This procedure, therefore, should be made mandatory as a reasonable precautionary measure. The cost for performing such tests which may be placed upon the producer or user of such chemicals intended for use as food additives, while considerable, are minor indeed when compared with the expenses forced upon even a few consumers contracting cancers from the ingestion of a chemical additive introduced into the food because of inadequate or incompetent pretesting for carcinogenic properties. Cost of medical care, loss of income, and public care of dependents of such cancer victims would consume within a short time manifold the cost of pretesting of chemicals for carcinogenic properties. Not only moral but ultimately also legal considerations in fact should make pretesting of food additives a definitely economical measure to the food processing industry.

Actual and potential dietary cancer hazards form one of the various segments composing the environmental cancer panorama, which has assumed during recent years increasing importance as a public-health problem, since it forms the basis for a future large-scale control of cancers by primary preventive measures. For planning such a program on an adequate and comprehensive scale corresponding to that leading to the preventive and sanitary control of infectious diseases, proper consideration should be given to the fact that in many instances

the same environmental carcinogens affect members of the general population for various reasons and from different sources. It therefore may be advisable and profitable to organize any future attack on these health hazards of modern age from one central agency capable of assessing the importance of the various facets and properly integrating the efforts and facilities required for their control.

DISCUSSIONS AND DEBATE ON FOOD ADDITIVES SUMMARIZED BY WM. B. DEICHMANN, PH. D., DEPARTMENT OF PHARMACOLOGY, UNIVERSITY OF MIAMI, SCHOOL OF MEDICINE, CORAL GABLES, FLA.

On August 6 and 7, 1957, a group of scientists met in Washington to discuss the considerations pertaining to the necessity and safety of food additives. They had been selected by the National Academy of Sciences and invited by Congressman John Bell Williams, Democrat, of Mississippi, to appear before the Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce of the House of Representatives.

To invite a panel for "discussion and debate" was a departure from the time-honored method of inviting or subpenaing individual scientists who subsequently testified as expert witnesses, and who were cross-examined by attorneys on scientific matters pertaining to proposed legislation.

The panel discussion on food additives was modeled after the Salk vaccine panel which had proved to be an outstanding success primarily because the scientists debated, rather than presented, a certain point of view.

To get the food additive panel underway, Congressman Williams had requested Dr. Detlev W. Bronk, president of the National Academy of Sciences, to assist the subcommittee in the selection of a panel.

Dr. William J. Darby, head, department of biochemistry, and director, division of nutrition, Vanderbilt University, School of Medicine, Nashville, Tenn., accepted the chairmanship of the panel. The members represented three fields of major interests: "Food industry," "Toxicology and pharmacology," and "Cancer." Knowledge concerning food technology was represented by three scientists: They spoke first, namely, Dr. Emil Mrak, chairman, department of food technology, University of California, Davis and Berkeley, Calif.; Mr. Harry K. Murer, manager, research center, General Foods Corp., Tarrytown, N. Y.; and Dr. F. M. Peters of the research laboratories, Quaker Oats Co., Barrington, Ill.

Dr. Mrak pointed out that certain agents are added to foods to maintain aesthetic and nutritional values, to improve accetability (color, flavor, texture), stability, convenience to the consumer, or to reduce their cost of production. But he added that the chemicals must be safe and that they must not be added for the purpose of deception. Dr. Mrak and Dr. Darby then called attention to the Food Protection Committee's report, and to the report of the First Joint FAO/WHO Expert Committee on Food Additives (World Health Organization, Geneva, 1957). This latter report was entered into the record.

Mr. Murer emphasized that the usefulness of each additive for each food must be determined technologically and that each must be judged on its own merits. In fact, he said "We cannot make a blanket statement that this or that chemical will be useful for any particular purpose." He continued, "I certainly would like to emphasize the fact that we cannot and should not in any way stifle progress which brought, in my estimation, such excellent food supply to us. No one in the food industry doubts the fact that we should put safety first, but as far as I know, all food manufacturers have in fact, for a long time, been quite conscious of the safety factor."

Dr. Peters pointed out that: "Nature does not always produce perfection. A striking example is the bread of the Mexicans, coming down from the Aztecs. This bread, tortillas, is made by steeping corn with lime water. The act of adding lime to a food might appear pernicious to the uninitiated. However, the lime furnishes vital quantities of calcium to the diet of those people consuming tortillas. Proper formation of bones and teeth is impossible without sufficient calcium and, hence, it can truthfully be said that tortillas with their lime have been a lifesaver for generations of Central Americans. In the Mexican and Central American dietary, insofar as I know, there is no adequate substitute for tortillas.

"Cheese requires the addition of 'chemicals' for its production. So does yogurt. Whether it is an acid or enzyme produced by a bacterium or produced in a factory, the end result when placed in the food we eat is the same. Thus, it is

clear that chemicals, or additives, have been used in foods for centuries. When my mother couldn't get the apple jelly to jell she added a little pectin, although she had never heard of pectin—she called it rhubarb. She did know that a little rhubarb added to apple jelly made it jell better. Nature gives some apples enough pectin for jelly-making; but if nature fails, a food additive put in by human hands does the same thing.

"Much of that which we are doing with food additives involves a leveling off or standardization of the amounts of natural chemicals that nature has furnished. There is nothing much new or mysterious about it. I have mentioned acids and the alkali, lime, that have been used for generations. There are others, such as preservatives or stabilizers and antioxidants. This latter is merely a polysyllabic word for things that prevent destruction or deterioration from exposure to air.

"Some of us are prone to believe that everything in nature is benign. There are many horrible things in nature. Who would suspect that navy beans would kill a chicken, pig, or rat? Millions of tons or soybeans are grown each year. Unless properly heat-treated, soybean meal is very toxic for chickens. The common navy bean, raw, as the major source of protein in the ration of laboratory rats will kill them. We do not think of these as poison, but as common everyday food. But, in their natural state, they are far from harmless. Man must cause a chemical alteration within the bean or soybean before it is suitable for use as food."

All agreed that certain additives, properly used, are justified since they maintain nutritional quality and stability or aid in the processing of foods. It was warned that they should not be employed to disguise faulty processing or inadequate handling techniques, and that they should most certainly not be used to deceive the consumer. Whether flavors should or should not be used aroused much interest. According to Dr. Peters "all of the strawberries in the world would not be sufficient to make the amount of strawberry flavor that is now used in our food inustry. Hence, the same flavor is prepared in the laboratory, that is by chemical synthesis, but when we add this synthetic flavor, we add a food additive."

Dr. Darby interjected "that foods which are appealing to one group of people are not necessarily the same which would appeal to another." He was referring in particular to the influences of flavor, color, texture, and method of preparation. He continued "I think it has been pointed out rather clearly that the use of additives is not something which is of recent vintage, and that there are certain technological justifications for their use."

The remaining portion of the first day was given to the pharmacologists and toxicologists who were primarily concerned with the evaluation of the safety of a food additive. They spoke in the following order: Dr. R. Blackwell Smith, president, Medical College of Virginia, Richmond, Va.; Dr. William B. Deichmann, chairman, Department of Pharmacology, University of Miami, School of Medicine, Coral Gables, Fla.; Dr. Maurice H. Seevers, chairman, department of pharmacology, University of Michigan, Ann Arbor, Mich.; Dr. Henry F. Smyth, Jr., Mellon Institute, Pittsburgh, Pa.; Dr. Howard C. Spencer, biochemical research department, Dow Chemical Co.; and Dr. John H. Foulger, director of medical research, E. I. duPont de Nemours & Co., Wilmington, Del.

Dr. Blackwell Smith made it clear that toxicity is a relative matter and that it, therefore, means nothing if one states that an additive is "poisonous" or that it is "toxic." He added "the matter which needs to be determined is whether a particular chemical compound has the inherent capacity to produce injury, whatever it may be, and whether it will be safe when it is used in a particular fashion." His second point was, that it is not possible to establish any standardized set of procedures which might be made obligatory and which would apply to the testing of all substances proposed for use as food additives. He emphasized that "scientists qualified by training and experience must be relied upon to design the experiments needed in each specific case, and to interpret the data." His last point was in reference to the "safe level" of a food additive. He pointed out that it is generally believed that when this concentration is not exceeded, it is extremely unlikely that harm will be done, but that there still remains an element of risk. It was his view that additives should confer some benefit to the consumer in order to justify this admittedly small, but nevertheless inescapable risk.

Dr. Deichmann explained what is meant by acute, subacute, and chronic experimental studies; and he outlined the questions raised by the phramacolo-

gist or toxicologist whose job it is to determine the mechanism of action (pharmacodynamics) and the metabolism of a food additive in experimental animals.

Dr. Seevers initiated his remarks by emphasizing that we must distinguish between "toxicity" and "hazard." He agreed with statements made by the previous two speakers, namely that the investigation of each food additive must be considered as an individual problem. He continued "there are different levels of safety requirements. In the drug field, for example, no one would accept a high toxicity level for a mouth wash or for a pain killer sold over the counter. The standards for these are: low toxicity and a very high degree of safety. The same standard applies to foods. On the other hand, in medicine if we have a disease which is 100 percent fatal, such as certain types of cancer, we are justified in using compounds which are very highly toxic, and we actually do use compounds which have been known to kill. Safety, therefore, is only a relative matter, whereas toxicity refers to a fairly standardized procedure which may be determined in any animal, including man, for every drug and for every mode of administration."

Dr. Seevers reemphasized that the hands of the individual who carries out the toxicological investigation and the persons responsible for evaluating these data should not be tied by legislation. These experts must rely on their experience and judgment in determining the factors pertaining to the safety of a new additive. He added that this applies not only to the original investigators but also to the men in the Food and Drug Administration who are ultimately charged with the responsibility of making decisions pertaining to safety.

Dr. Henry Smyth, who represented a large chemical industry, spoke of the enormous volume of pretesting of chemicals in experimental animals that he and his associates have been conducting for years to safeguard the health of the people who manufacture and handle new compounds or who may use, consume, or otherwise come in contact with these chemicals. He added, "We have advised our corporation and its customers for years that the intended use of a new chemical will be safe and proper. A compound would have never appeared on the market if we could not have made this statement." He continued that it is the expected market which must justify the expense involved in a toxicological investigation. This is quite a factor. Most people do not realize that it takes approximately 3 years and from forty to seventy thousand dollars to obtain the information desired by the United States Food and Drug Administration to judge the safety associated with the use of a new chemical. And, it may be well to add at this time, that industry is doing this voluntarily, for according to our present laws it is up to the Federal Government (not industry) to prove that a certain chemical is harmful.

Dr. Smyth continued, "In our laboratory, we study the changes that take place with the chemicals in the bodies of each kind of animal that is convenient to study. Unfortunately, we must injure some of the animals so that we may determine the exact nature of the injury and estimate, based on our own experience and the work of others, what would be the likely injury to humans from the same chemical. Subsequently, we do sufficient exploratory work on humans to determine how the human body changes these chemicals." He emphasized "that the species of animal which changes the chemical in the same way that the human changes it, is the species which gives us the best prediction of how much of the chemical a human can stand." Dr. Smyth then made a plea that the United States Food and Drug Administration see that all of the data pertaining to the toxicity and metabolism of food additives upon which they base tolerances and clearances, are published for all scientists to scrutinize, for better protection of public health. In industry one often speaks and sets limits of tolerance in terms of parts per million, generally referred to in scientific literature as "milligrams per kilo." It was Dr. Smyth's feeling that no one really had a clear concept of what one part per million actually means. He gave the following example which I am sure will be remembered by all who attended the session: "You have 1 part per million if you put 1 drop of a solution in 16 gallons. What is 16 gallons, well it is 80 fifths of whisky, which a good many people can visualize, that is 1 part per million."

Dr. Spencer, representing another large chemical industry, supported Dr. Smyth's statements and repeated that what we are concerned with in the toxicological laboratory is to make sure that chemicals are handled safely in production and that they are safe for human beings after they have been sold. He emphasized that the principle of pretesting is firmly established in the chemical and food industries as shown by the work in industrial, university, and

consulting laboratories. He pointed out that in his laboratory are men with basic training in chemistry and biochemistry, pharmacology, physiology, nutrition, pathology, veterinary medicine, human medicine, and other sciences, and that they work as a team. He repeated what previous speakers emphasized, that laboratory procedures cannot be stereotyped, that a specific investigation must be geared to a particular compound and its contemplated use, and that no set of procedures can replace the judgment of a competent investigator and his interpretation of the results. "Just as the design and conduct of the experiment is the responsibility of the scientists, so also is the evaluation or the interpretation of these data." He quoted a statement of Dr. Arnold J. Lehman, Chief of the Division of Pharmacology of the United States Food and Drug Administration, "There can be no formula, ration, or substitute for the mature and considered judgment of men fitted by experience and training for making the final recommendation. In the last analysis, the caliber of the men conducting the experiments and making the evaluations determines the usefulness of animal toxicity data."

Dr. Foulger pointed out that our industrial workers are exposed, first, to the chemicals with which, despite all our efforts they may have contact in the chemical industry and, secondly, to the same type of food as the general population is eating. He pointed out that in his own company are records of nonindustrial illness as well as industrial; that over the years the loss of time from nonindustrial illness has decreased; that no new or mysterious diseases have occurred. His conclusions were that since the workers of his company are in double jeopardy and often exposed in their industrial work to much higher concentrations of some of the same chemicals that are used in food processing (or similar chemicals) there is no justification for the belief that there is developing a high incidence of illness due to obscure diseases produced by chemicals.

At 12:15 p. m., the subcommittee adjourned to reconvene at 10 a. m. August 7, 1957.

Representative John Bell Williams opened the Wednesday morning meeting. He thanked Dr. Darby and his associates for having taken the time and trouble to come to discuss the very important problem involving food additives. He turned the chair over to Dr. Darby, who then summarized some of the highlights of the previous day. Dr. Darby went on: "A number of the panel members pointed out rather clearly that it is necessary for us to continue to use chemicals in the production, processing, and storage of foodstuffs * * * It was repeatedly emphasized that each additive is a different chemical substance, and that allowances must be made depending on the specific use for which an additive is proposed * * * one cannot judge safety without some knowledge of the use to which an additive is to be placed, therefore," he continued, "it would seem in any regulatory procedure there should be an allowance for what we might call the individuality of additives—the individuality of appraisal of safety * * * I think, further, that several of the panel members expressed repeatedly the scientific nature of decisions or judgments as to safety, and, therefore, the responsibility for scientists to make judgments in this area." Dr. Darby then introduced the speakers. They included: Dr. Morton L. Levin, director, assistant commissioner for medical services, State department of health, Albany, N. Y.; Dr. Paul R. Cannon, chairman, department of pathology, University of Chicago, Chicago, Ill.; Dr. W. C. Hueper, National Cancer Institute, National Institutes of Health, Bethesda, Md.; Dr. Emmerson Day, chief, division of preventive medicine, Sloan-Kettering Institute for Cancer Research, New York, N. Y.; and Dr. Herbert E. Carter, head, department of chemistry and chemical engineering, University of Illinois, Urbana, Ill.

Dr. Levin was the first speaker. He gave some of the background on what is known about the causation of cancer in man. He pointed out that "cancer, in distinction from most other diseases, is a disease for which we have multiple causes, that is, the same type of cancer can be produced by several different agents. However, for the most part, most cases of human cancer are of unknown causation." He continued: "We must remember that cancer in the human population today, particularly in the United States, will affect 1 out of 4 individuals at some time during life. We cannot rule out the possibility that substances which we do not suspect today may actually be causative of cancer." Dr. Levin told the panel that chemical causation of cancer was originally discovered by observation of human beings. In regard to the relation of cancer in man to that in animals, he had the following to say: "With respect to the comparability of cancer as produced in animals and in man, most of the known chemical causes

of cancer in man are known also to produce cancer in animals. There are at least two exceptions—arsenic and chromate compounds—which are considered to be cancer-producing in man but have not been shown to be in animals. So we cannot definitely exclude the possibility that a chemical, even though it may be negative in animals, may still be a carcinogenic chemical in humans." Dr. Levin then proceeded to describe the epidemiological methods which are being employed for studying a suspected relationship between various agents and the appearance of cancer in man. He went on that the most practicable epidemiological methods involve the study of special populations. He pointed out that "actually a good deal of what we know about chemical causes of cancer has been determined by precisely such studies, by studies of persons exposed in an occupation to a particular agent." Dr. Levin made a plea for more extended human epidemiological studies. He concluded, "Our first line of defense in studying the possible carcinogenic effect of such substances as food additives should be animal experimentation, but we cannot rely exclusively on animal experimentation for the possible discovery of such effects."

Dr. Cannon stressed morbidity and mortality statistics. He pointed out that medical knowledge and diagnostic facilities—in relation to cancer—are improving, but, he continued "there is one handicap that has been with us and will be with us for many years. That is the small number of persons dying in this or any other country who are subjected to post mortem analysis after death with microscopical examination by competent pathologists to determine the presence of cancer and the type." He emphasized the importance of epidemiological studies, and the collection and evaluation of the evidence. He made a strong plea that more people should become interested in the prevention of cancer rather than cancer after it has developed, and after it has become irreversible. He concluded "If everyone would get interested in helping to find out how cancer starts, what causes cancer, we would come out in the end much better than trying to meet it headlong after it has developed."

Dr. Hueper followed by presenting the established carcinogens for man, namely: arsenic as potassium arsenite, benzene, certain chromium and nickel compounds, estrogens (in males under certain conditions), asbestos, benzidine, beta-napthylamine, para-aminobiphenyl and certain rays including alpha, beta, gamma, Roentgen, and ultraviolet rays. Certain constituents of petroleum, shale oil, lignite oil, coal tar, pitch, creosole, synthetic coal oils, carbon blacks and soot, and impurities in crude isopropyl alcohol are also on the list of established carcinogens but the individual chemical compounds in these crude preparations have not definitely been identified or isolated. He then listed the suspected human carcinogens as well as those compounds which under proper conditions of exposure are known to have produced cancer in some of the experimental animals and are a part of the human economy. He warned against the human use of compounds which are apparently metabolized in the dog to beta-naphtylamine. He stressed the importance of suitable experimental animals, that is, animals presenting counterparts of man. He continued "We have to consider the fact that materials which may be carcinogenic are ingested for our entire lifetime. Of similar importance are possible carcinogens present in our general environment like the air, the soil, or the water. The situation must be taken seriously * * * since the effects of carcinogens on the tissues are summation effects, and because I don't believe that one can establish a safe does of a carcinogen" * * * He concluded "I suppose that it would be a wise precautionary measure not to add any chemicals to our food supply which either produced cancer in man or in experimental animals."

Dr. Day then took over * * * "to determine causes of cancer in man and bring about control, we believe that the data which are to be studied must originate in man * * *. We then proceed into the laboratory with animal experimental work as an adjunct or tool to help identify possible activators or methods of action in the production of cancer, but never believe that the demonstration of carcinogenicity of the substance in animals proves that it is a carcinogen to man. I believe that is a trap that we must not enter into. All of the animal work in the world, from my point of view, does not help us understand or control cancer in man unless there are counterparts in man's experience * * * anything short of this I feel is inadequate to prove the cause of cancer in man." He agreed with Dr. Levin that * * * "we must continue by all methods that are available to extend basic epidemiologic studies of population groups. Then we must use the animal experimental work as it applies as an adjunct to studies in man."

Dr. Carter emphasized that in the problem of dietary carcinogens we are more interested in the results of oral administration than in the carcinogenic effects of a chemical on the skin, urinary bladder, or one that may have been injected under the skin, and pointed out that entirely too few studies had been made of the oral administration of possible carcinogens. He agreed with Dr. Day that statements should not reach the public which could be misinterpreted because of the scientific language used or for other reasons. He pointed out that the word "paraffin" is often misunderstood. Paraffin to a chemist means one thing, to a physician it may mean something else, while the housewife visualizes a third possibility. Everyone agreed that premature information can bring only panic and fear and contribute nothing to an intelligent approach of the cancer problem. He warned against generalization purely on the basis of chemical structure. Dr. Carter was more optimistic on finding the solution to the cancer problem than some of the previous speakers. After pointing out the importance of studying cancer at the cellular level, he continued "there will be many ways in which it may be possible to find out how a cell reacts to the presence of a carcinogen long before the final demonstration of the irreversible transformation into a cancer cell itself. And, from this standpoint, I think progress is likely to come. Certainly, I would agree wholeheartedly with Dr. Hueper that a proven carcinogen should not be used as a food additive. However, I would underline that both 'proven' and 'carcinogen' must be properly defined."

During the discussion, Representative Robert Hale (Maine) raised the question whether ingestion of one dose of a certain carcinogenic chemical is likely to produce cancer, or whether the effect is produced only by eating food containing this chemical over a prolonged period of time. Dr. Levin answered "I would say for the most part that the answer would be that one dose would be insufficient * * * it is conceivable, for instance, that one would ingest a radioactive substance which would remain in the body indefinitely and thus would exert its effect continuously and ultimately produce cancer; but for an ordinary chemical, I cannot think of any chemical for which one dose would be sufficient to produce cancer in man." The discussion that followed brought out that it required either repeated or long-continued use of a carcinogenic agent to produce cancer in man. Dr. Foulger emphasized that animal testing is a drastic and severe procedure. He continued, compounds that we wish to investigate are fed to certain animals, particularly rats, during their entire life, while humans do not necessarily eat day after day the same foods and, therefore, do not ingest the same additives day after day. He pointed out again that pretesting of chemicals on experimental animals has gone on for years and that "it has gone on voluntarily" to safeguard the health of industrial workers and the population in general. Representative Joseph P. O'Hara (Minnesota) then raised the question whether "there is some need of further legislation in the field of food additives." Dr. Fougler answered, recommending that what has been done voluntarily in the past should be made mandatory in the future, and that we should turn over to the Food and Drug Administration all toxicological information obtained in industrial laboratories.

Representative Isidore Dollinger (New York) then wanted to know how much independence or how much leeway or how much latitude the toxicologist of an industrial company has in making the recommendation whether a certain food shall or shall not be sold on the market. He continued "What I am driving at, Doctor, is this: Suppose you and your research panel indicate or find that there is some question as to the advisability of the use of an additive, and suppose the sales department or some of the other people want to sell the item because the company may have invested money in its manufacture. Suppose they differ with your views and think it is safe enough for use. Can you overrule the front office? Or, will you have to take orders from them?" Dr. Foulger answered that if the sales department would ignore the advice of the company's scientists, sooner or later the Food and Drug Administration would hear about it, and that all the FDA would have to do is to write to the newspapers—over the signature of the Commissioner or the Secretary—saying that this certain matter has come to their attention and that the particular chemical is dangerous. Obviously, there will be no further trade in that business. Dr. Smyth, who works in the interest of a large chemical manufacturer, added "I have no authority in that corporation, I am an adviser there." He continued "It is inconceivable to me that my company would dispute our conclusions, * * * it just would not happen with this corporation that they could overrule the toxicologist and go ahead and sell" (a material that we would not consider safe).

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Representative George M. Rhodes (Pennsylvania) wanted to know whether "any scientists employed by an industry who wants to keep his job would dare to express an opinion if it were in conflict with that of the company." Dr Carter vouched for the honesty and sincerity of the scientific people whose job it is to advise management. He had the following to say "I am head of one of the largest chemistry departments in the United States. I have been there for 25 years. During that period of time, we have sent on into industry on the average of 40 or 50 Doctor of Philosophy scientists each year. This year we sent 60 * * * I can say that of each we keep close contact whose advancement we are concerned with, whose positions we want to know about—that I have never known of a single case in all of these people where a man, a scientist, was fired for stating his honest opinion, for presenting thef acts and for sticking up for those facts." Apparently some testimony to the contrary presented during previous hearings prompted questions of this nature. Representative Dollinger ended the discussion by adding that there might be situations where other companies who have no representatives here would stoop to such a situation [but] that is what we are trying to protect the public [from].

The possible carcinogenic action of currently used food additives aroused additional interest. Estrogens in chickens and beef were discussed but no conclusions were arrived at.

The honesty and sincerity of industrial companies came up for further discussion. Dr. Murer answered and referred to a particular compound which they had planned to obtain from another company for use in their food industry but which, during pretesting by his company, was not found to be sufficiently safe. He continued: "We called it to the attention of the people who were manufacturing this compound, * * * I think it represented something like 80 percent of their business, and I can assure you, that with no further evidence than that which they saw in our own laboratory, they stopped their manufacture and went out of business in 24 hours." Dr. Spencer added that his company had synthesized an ingredient of certain flavoring agents which had been in use for about 75 years. Recently, information came to their attention that this material had certain properties that they did not know about. When he informed his management of these previously unknown undesirable properties, the flavor was taken immediately off the food-flavoring market.

Dr. Deichmann referred to studies with four dogs which had pinpointed a certain chemical as the one most likely responsible for carcinogenic effects previously observed in a few workers who had been exposed to a variety of chemicals. On the basis of these observations, the synthesis of the chemical was stopped immediately, and management of the particular company announced to the whole chemical industry that the manufacture and sale of the chemical had been discontinued. Dr. Peters added: "Scientists have two great possessions. First, the desire and ability to ascertain the facts—to ferret out the truth. Second, and equally important, is the scientist's reputation for absolute honesty. There is nothing that will ruin a scientist professionally as quickly as will his departure from the truth about a scientific experiment. No industrial scientist can possibly afford to speak other than the truth when he is asked for the facts. In my particular company, the law department will never O. K. any formula or technical advertising claim until it has been approved by the research department."

Dr. Williams then read recommendations that had been made by the American Cancer Society. In brief, they included the strengthening of the Food and Drug Administration, the institution of requirements to test the safety of human food additives, the testing of additives in respect to their carcinogenic properties in experimental animals, the withholding of additives from use until their safety has been demonstrated to the satisfaction of the Food and Drug Administration, and the recommendation that no substance be approved if found to induce cancer in man or animal. Dr. Deichmann added that we must choose our experimental animals and methods with great care, that we should not condemn a chemical as food additive solely on the basis that it produced cancer in a particular animal. He added that he would not necessarily condemn an additive which produced skin cancer in a hypersusceptible mouse, but that he would most certainly not consider a compound as additive that produced bladder cancer in the dog regardless of the route by which the compound entered the dog's body. Dr. Cannon came back to the legislative problem which, incidentally, was discussed only briefly. He warned that it is very easy to pass a law, but that because of the extreme complexity of the problem, it is very

difficult to ascertain in the relatively near future whether the law passed was a wise one.

Chairman Darby referred once more to the magnitude of the scientific tests involved, particularly if it should become necessary to test every substance considered as a food additive. In referring solely to the food color problem, he estimated that these studies—considering only procedures which seem quite reasonable—would consume something like 25 years of manpower of the present Food and Drug Administration. He emphasized that laboratory methods for testing and safety of food substances must be reviewed and reappraised constantly to allow for flexibility and progress. In response to the question as to why certain additives might be withdrawn which had already been approved, he answered "I don't believe that this necessarily indicates inadequate pretesting. It may indicate inadequate pretesting in light of persent-day knowledge, but not necessarily. * * *."

Representative John Bell Williams then thanked the chairman and the committee for having come to Washington and for having testified as a panel on a highly complex problem. He referred to a previous meeting several years ago and continued "We had a scientific witness on the stand and he had gone into a rather complex scientific problem, using scientific terminology throughout the testimony, and when he had concluded his testimony, I turned to my colleague sitting next to me and I asked him what he thought, if he would like to comment on that testimony." He answered "If he will just put it on the lower shelf I won't have so much trouble reaching it." Mr. Williams continued "I want to thank you gentlemen for keeping it on the shelf low enough for the committee to reach, most of it at least."

Whereupon, at 12:30 p. m., the hearing was adjourned.

Where Do We Go From Here?

An analysis of the testimony presented before the subcommittee on health and science of the committee on interstate and foreign commerce of the house of representatives

(By William B. Deichmann, Ph. D., professor and chairman, department of pharmacology, University of Miami, School of Medicine, Coral Gables, Fla.)

It was pointed out repeatedly during the panel discussion that food additives are different chemical substances and that most likely no two additives will be used under identical conditions. For this reason, stereotyped methods of pretesting cannot be applied. Each chemical has to be evaluated on its own in order to insure its safety under the conditions of its intended use. As Dr. Darby pointed out, "it is necessary to have some concept of use, regularity of appearance in the diet, and so forth, in order to appraise the problem or in order to appraise or judge safety." In other words, then, we must be sure that food additives are not toxic, and in addition that they will not contribute to, or produce, cancer.

Pharmacologists realize that with thoughtful planning, discovering the pharmacological actions and the toxicity of a new additive represents a straightforward problem. How to determine the possible carcinogenic potency of a compound is another matter. The fact is that we do not have a dependable straightforward method of approach; we do not even know what goes wrong in an organ, in a tissue, or in a cell to set off the trigger, causing cancer.

The first question to settle is how we should start. Shall we agree with Dr. Day, who stated, "to determine causes of cancer in man and to bring about control we believe that we must study data which originate in man" and who continued, "all the animal work in the world, from my point of view, does not help us understand (how) to control cancer in man unless there are counterparts in man's experience"? Or shall we agree with Dr. Levin, who stated, "our first line of defense in studying the possible carcinogenic effect of such substances as food additives should be animal experimentation, but we cannot rely exclusively on animal experimentation for the possible discovery of such effects"? Dr. Levin described four epidemiological methods supplementing animal studies, which are used to trace the cause of cancer. He considered his third method, "the study of special populations," particularly suitable. By special populations, he meant people engaged in the manufacture of a particular chemical. Or should we exert our primary influence as recommended by Dr. Carter, who was more optimistic than some of his colleagues and who believes that progress is likely to come from the study of a single cell? To quote him,

"It is possible to study energy production by a single isolated cell. There will be many ways in which it may be possible to determine how a cell reacts to the presence of a carcinogen long before the final demonstration of the irreversible transformation into a cancer cell itself."

Let's look at each of these approaches in somewhat greater detail. It has been stated repeatedly that most of what we have learned of human cancer was discovered in man. This is correct, and perhaps for this reason we should confine our studies to man. In this case, the simplest method of arriving at an answer would be to divide our population into various groups, experimentals, and controls, to feed them various suspected carcinogens, and then to sit back and wait 20, 30, or more years for some type of cancer to develop. Obviously, this is not a method that we would choose, but, judging from the prevalence of human cancer, are we not actually doing this in an uncontrolled way?

Let me explain. For the past years, many of us have undoubtedly absorbed, perhaps by inhalation, by ingestion, or possibly by absorption through the skin, certain chemicals which are responsible for at least certain of the cancers with which many are afflicted today. This certainly applies to some of the industrial population or to people living in highly industrialized areas. The causes of about 99 percent of the human cancers are not known. Exposures to a compound such as beta-naphthylamine have in several well documented instances led to cancer. Perhaps other not yet identified carcinogens are now in use. Certainly cancer is a common affliction. Records show that 1 of each 4 persons will suffer from this disease sometime during his life.

Epidemiological studies have pinpointed certain chemicals as carcinogenic agents. But, since the first appearance of cancer usually follows a latent period of 15, 20, or more years, we must be lagging 15 or more years behind the responsible contact if we place much reliance on such methods. To those who attach undue significance to epidemiological studies, I should like to say that these investigations have detected the causes of considerably less than 1 percent of the human cancers. It is true, as Dr. Levin pointed out, that most of what we know about chemical causes of cancer originally was discovered by observation of humans. But are we committed to this method exclusively? Most of what we have learned about lead, mercury, arsenic, and certain other poisons, was also discovered in man. But certainly for the effects of new industrial materials we do not continue to look to man as the experimental animal of choice. Everyone in the fields of occupational medicine, industrial hygiene, and toxicology realizes that pretesting of chemical compounds in experimental animals has prevented during the past 30 years untold intoxications in man.

If we are unwilling to accept experimental animals for the testing of suspected carcinogens, then why do we assume that drugs which we use in the treatment of certain human cancers should be effective just because they demonstrated certan desirable properties in experimental animals?

I wholeheartedly agree with Dr. Day that all of the animal work in the world does not help us unless there are counterparts in man's experience. By the same token, one might say that cancer in the mouse does not help us to understand cancer in the rat or dog unless we find such counterparts. We know from pharmacological and toxicological studies conducted in various animal species that counterparts of man's response exist in many of our smaller mammals. For instance, the rhesus monkey is excellent for the production and testing of vaccines that are used for prophylaxis of poliomyelitis in man. All pharmacologists recognize differences among species. They have learned to use certain of their organs or structures as counterparts for predicting effects for man. For example, from carefully conducted animal studies, it is entirely possible to predict with a fair degree of accuracy just what a certain compound will do to the blood pressure, to the heart, to the lungs, and even to the mood of man. This type of pretesting has been adopted so extensively that no pharmaceutical company would consider a new compound as a drug without animal studies, and no ethical industrial company would manufacture or sell a new compound without having previously obtained a favorable report from the toxicological laboratory.

The point is that there are many counterparts of man in animals and that the pharmacologists have learned to use these counterparts to obtain pharmacological information applicable to man. We simply have not exerted ourselves intensively enough to find counterparts in animals which are suitable for solving the human cancer problem.

Some scientists are not willing to accept the concept that animal data can point to certain clues in the human cancer problem. I admit that unjustifiable

conclusions have been drawn from "mouse-painting tests" and related studies, but this does not justify discrediting experimental animal data. Dr. Day spoke of epidomiological studies and animal tests as follows: "There are a number of instances where very helpful work started with * * * epidemiologic data. * * * We then proceeded in the laboratory with animal experimental work as an adjunct or tool to help identify possible activators or methods of action in the production of cancer. * * *"

What makes animal experimental work a tool to help identify a carcinogen unless animal tissues had these properties before epidemiological studies pointed to a certain compound as a possibly carcinogenic agent? Just why should we emphasize epidemiological methods instead of animal testing of a suspected human carcinogen?

There are other investigators, however, who have gone to the other extreme. Dr. Hueper would not use any chemical as a food additive which is known to have produced cancer in an experimental animal. Dr. Carter agrees with Dr. Hueper that a proven carcinogen should not be used; however, he wants to have the words "proven" and "carcinogen" properly defined.

If we accept Dr. Hueper's yardstick, then we condemn a multitude of chemical compounds, including two of our most important foods; namely, glucose and fructose. When these carbohydrates are injected subcutaneously in a relatively large dose into rats, they will produce sarcoma at the site of injection. Table salt will produce similar effects. It has been said that 25 percent of all chemicals are capable of producing skin cancer in either the rat or mouse. Studies with embryonic animal tissues will show even higher incidences of carcinogenicity, somewhere between 40 and 50 percent. Investigators who are in favor of embryonic tissue precancer testing have claimed that with this method it is at least possible to select compounds which are not carcinogenic. But this is an unwarranted conclusion since compounds which are harmless and safe in embryonic animal tissues may still be carcinogenic for man.

From animal studies we have learned the following:

1. There is a direct relation between the dose of a carcinogenic agent and the appearance of cancer (dimethyl aminoazobenzene; dimethyl aminostilbene; radiation).
2. In contrast to the ordinary toxic effects of a chemical, the effects of a carcinogen are cumulative. Therefore, "no dose" regardless how small is inconsequential.
3. Local irritation or injury, or cancer predisposing agents, or so-called cocarcinogens play their role in the production of cancer.
4. The length of life of individual members of an animal species largely determines the incidence of tumor formation, of particular significance in recognizing mildly carcinogenic agents, etc.

For each of these four conclusions counterparts in man can be cited. But what we need are additional counterparts, for instance, 1 or preferably 2 animal species in which we can demonstrate that a given chemical produces the same or at least a similar malignancy as in man. The bladder-cancer dog is a good example.

In advocating more intensive and broader animal research, I nevertheless agree with Dr. Carter that the real advances are likely to come from the biochemical laboratory. We must know what happens in cells (and these need not be human cells) before we will ever really know what went wrong in man or animals afflicted with cancer.

Animal studies then would be given second place with the primary aim of searching for human counterparts. Since we are concerned with the precarcinogenic testing of additives, I would suggest that we initiate studies as follows:

1. Feed each compound to as many species (mammals) and for as long a period of time as possible, including at least the rat and the dog and preferably other animals, not necessarily those used widely in the past.
2. Start feeding the compound to weanling males and females.
3. Feed pregnant females, and conduct reproduction studies.
4. Start groups large enough to provide a significant number of survivors living to a ripe old age.
5. Give careful consideration to the feeding of a well balanced basic diet, one that will neither inhibit nor support the formation of cancer.
6. Consider administering the compound at the same time by several other routes (application to the skin, subcutaneous injection, etc.) and
7. Maintain an adequate control group.

Add to these fundamental requirements some consideration of the strains to be used. Evaluation of the data will not always be an easy matter since spontaneous tumors will appear, at different sites, in treated and in untreated animals. Hence an adequate number of control animals is critically important. If the results are significantly positive in a rat, dog, pig, or monkey, etc., feeding experiment, then there is no question that the compound must be condemned as a food additive. If the results of the feeding experiment are inconclusive, then the data of cutaneous, subcutaneous or other studies may well provide the answer. If only one mode of administration other than ingestion should induce a significant number of malignant tumors, than the data need careful evaluation. Whether such information should or should not eliminate a compound as a food additive will have to depend on the species used, doses administered, method of administration or implantation, and other factors such as the importance of the contemplated use of the additive; whether it is to be added to maraschino cherries (for use in old-fashioned) to chewing gum or dill pickles, or to foods such as milk and meat.

When dealing with extremes, few people will have difficulty in reaching a decision. To quote Dr. Robert Eckhardt (private communication) "2-acetyl aminofluorene is one good example. It produced many tumors at many sites in many species and by many routes of administration. Few would argue with not permitting it in our food. But what about the material that produces few tumors in few sites in few species by few routes of administration? Here, it seems to me the above contention becomes all determining. If the additive is to be used in a food, like milk, which constitutes 27.6 pounds out of 67 pounds of processed food consumed each week by the average family, I think we would all hesitate to use it." Living conditions and standards differ considerably in different parts of the world. For instance, an additive "might be banned in the United States where the average life expectancy is 69 or 70, but permitted in India where the average life expectancy is 25. While lowering the life expectancy in the United States to 60, it might raise the life expectancy in India to 40, still too low to be in the really high cancer incidence range. Also 10 or 20 years from now it might be banned in India where once it was permitted. As our life expectancy increases to 80, 90, or 100 years, perhaps we may ban things we now accept."

Animal experiments will do much to give us an answer to the human cancer problem, and this is actually the best that we can hope for. There is no guaranty of certainty for those who plan to invest fifty to seventy thousand dollars for 3 to 5 years of animal research, that the data will provide a clear-cut answer. Since such studies are so costly and time consuming, each contemplated food additive must obviously be considered individually. We cannot exclude the possibility that a compound, negative in animals may still be carcinogenic in humans. These are cold facts, but in spite of reservations, animal studies are the most promising tests that will give, at this time, even suggestive information that a chemical is not carcinogenic for man.

Human epidemiological studies are important. They can bring to light those carcinogens missed by animal studies; they will discover others which were never subjected to a laboratory investigation. The importance of post mortem examinations and microscopical studies or organs and tissues showing the presence and type of cancer is equally obvious.

Our final thought. Since most of us confine our research to one particular area, we are inclined to draw general conclusions from individual bits of information. Obviously we must use all available data, not only results from animal studies but also those derived from biochemical, epidemiological, pathological, and other investigations. In addition, we must most carefully evaluate all facts and factors which surround the specific use of a material before deciding that the compound is safe, or that it should not be used as a food additive.

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Perspective Versus Caprice in Evaluating Toxicity of Chemicals in Man

Chairman's Address [1]

(Maurice H. Seevers, M. D., Ph. D., Ann Arbor, Mich.[2])

Life in these United States in the mid-20th century is so dependent on the products of chemical technology that no field of human thought or endeavor can ignore its dominating influence. Given reasonable time, the chemist appears to be able to construct a product to meet almost any set of specifications, the limiting factor being the imagination of the designer. Developments in this field have moved forward so rapidly in the last two decades that even the pharmacologist can scarcely keep abreast of the influx of new drugs, while the toxicologist is swamped with the multitude of agricultural, industrial, and household chemicals that are flooding the market.

Many of these compounds are highly toxic by any standard. Others are potentially capable of effecting long-range biological actions about which little is presently known. The public, ignorant of these effects, deserves and expects protection against unlimited exploitation of these new substances. The question is how much protection a Government can be expected to guarantee to the Nation and how it shall be accomplished. It would appear to be in proper perspective to say that the least the public should expect is that the algebraic sum of beneficial and detrimental effects of any chemical substance represent a significant positive balance in favor of benefits to the person and/or the state. By the same token, it seems out of perspective to attempt to protect the public against every conceivable contingency that may occur. The quantity of technical information concerning the biological actions of old and new chemicals, even in that circumscribed area of principal interest to the physician, the effects of chemicals on man, is now so great as to pose a most difficult problem in medical education, since it is to be expected that the medical student, the general practitioner, and even the medical specialist can assimilate only a very small fraction of this mass of material.

American physicians are indeed fortunate in being able to inform their patients that drugs purchased on prescription or for self-medication are almost certain to be of proper identity, purity, quality, and quantity. This situation is virtually guaranteed by the wise provisions of the Food, Drug, and Cosmetic Act of 1938, especially the new drug section, which requires approval in advance of distribution. In the main, fair perspective has been maintained in administering the act as it relates to drugs, and the medical profession has retained the initiative in this area, probably because it is better informed about the tools it uses daily. Drugs, however, represent only a relatively small fraction of the total problem of toxicity of chemicals for man. It is also the easiest fraction with which to deal, since a greater risk is permitted and toxicity is usually easier to determine. In the fields of food additives, pesticide residues, industrial exposure, and many other situations involving borderline decisions between toxicity and nontoxicity, the problems are exceedingly difficult. In these areas, the medical profession has lost the initiative, even in many situations in which its members are the only persons with competence to make decisions critical to the public welfare.

This is not surprising and may not even be seriously detrimental to the public welfare, since decisions based on this technical information affect every facet of human activity so profoundly that they represent legitimate concern of sociologists, economists, legalists, moralists, politicians, and internationalists, as well as physicians and biologists. It is almost axiomatic that areas of activity such as these, in which opinion must often substitute for lack of factual data, may also become the province of the crackpot, the self-styled scientist, and the well-meaning but misinformed reformer. Any of these persons may exert a powerful influence on the general public by posing as a champion of the individual safety and protector of the public welfare.

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[1] Read before the section on experimental medicine and therapeutics at the 102d annual meeting of the American Medical Association, New York, June 3, 1953.

[2] From the department of pharmacology, University of Michigan.

It would be surprising indeed if proper perspective were to be retained by all participants in a situation involving such a large number of points of view and so many selfish interests. Who should logically bear the responsibility for maintaining proper perspective in a situation that involves such a maze of conflicting forces? Obviously the principal responsibility for retaining perspective is in the hands of those who are authorized to administer the law and the regulations enacted under the law.

My purpose is to call attention to certain situations involving nondrug chemicals, food additives, pesticides, and other commonly used products. These facts should be of interest, since their implications represent a cause for professional as well as civic concern. As a pharmacologist, whose business it is to keep informed on matters related to toxicity, I am in a position to recognize and to view with alarm the gradually growing body of practical propagandistic pseudoscience that is being permitted to increase by those who are legally and morally responsible for retaining perspective, in order to fulfill what they believe, undoubtedly in all honesty, to be their obligation to the American public.

EXISTING LEGISLATION AND PHILOSOPHY

For approximately 50 years, the Food Division of the Food and Drug Administration has adhered to a basic administrative policy that no chemical shall be added to foods. This philosophy was first established, even prior to the enactment of the 1907 Food and Drug Act, by H. W. Wiley, who was then Chief of the Bureau of Chemistry, United States Department of Agriculture, the predecessor of the present Food and Drug Administration. There have, of course, been many decisions that are contrary to this policy, since it is difficult to consistently find scientific support for a negative position. It is not my intention to discuss the merits of this policy but to declare what I believe to be the results in loss of perspective from adherence to an administrative policy that is not based on sound scientific principle. Lest there be any doubt that such a policy is still in existence, I quote from testimony offered by Dr. Dunbar, the recently retired Commissioner of the Food and Drug Administration, before the House Select Committee To Investigate the Use of Chemicals in Food Products, the Delaney committee: "I feel that no chemical or no new chemical that is subject to any question as to safety should be employed until its possible injurious effect, both on acute and over a longtime chronic basis, has been shown to be nonexistent. In other words, any chemical that is proposed for use ought to be approved in advance of distribution in the food product to be utterly and completely without the possibility of human injury." Strict adherence to this statement would be to deny man the use of every chemical substance in view of the unquestioned fact that no method ever has been, or ever can be, devised that will permit an exact advance prediction of human hazard. In simple terms, no competent pharmacologist, toxicologist, or clinician will guarantee that there is no risk present in making available a new chemical for widespread distribution.

Although I believe that any philosophy based essentially on prohibition is impossible of scientific defense, my concern does not stem primarily from this fact. I am much concerned, however, as a scientist, about the methods used in the name of science to support an indefensible policy. These methods are essentially based on a studied attempt to confuse and mislead the public. My remarks are not intended to be an exercise in semantics, but I wish to make my point by relating what has happened to the terms, "toxicity" and "poisonous." These terms have become so misused and so abused by pseudoscientists, politicians, and others that they now connote almost any type of action, or reaction, whether biological, sociologic, or economic, that is reported to be inimical to the public interest. The shifting of these terms from a scientific to a lay connotation places the pharmacologist and the toxicologist, as well as the clinician, in a delimma. They are asked and expected to do the impossible. The principal task of the pharmacologist and the toxicologist is to supply sufficient basic information concerning the biological action and potential toxicity of a chemical substance on animals to warrant its preliminary clinical study in man as a calculated risk. What is the purpose of these studies if their application to man is denied? The a priori determination of calculated risk is an exceedingly complicated problem. In many instances it must involve the considered judgment of a large number of fully competent specialists in a variety of fields, including nonbiological areas. This is especially true when prolonged and extensive exposure of a whole population is involved.

As a result of the fact that so many persons may ultimately become involved and that so many decisions may be necessary to determine the calculated risk with accuracy, the easiest position for those in fields of great responsibility to assume is one that amounts virtually to complete prohibition based solely on absolute toxicity. This can be easily accomplished by the establishment of standards that are impossible to attain regardless of conditions of use, capricious and discriminatory decisions, and the like. Such a view is easy to assume since it is most amenable to regulation, requires the least energy to defend and administer, and requires no effort whatsoever to muster the support of the extremists, the misinformed, and the opportunists, to mention but a few. Strangly enough, the public appears to demand a share in deciding what shall be a calculated risk, although this seems contrary to the statements of representatives of this philosophy. A few examples will suffice. The per capita use of cigarettes increases each year in spite of the warnings about such deleterious effects as cancer. The per capita consumption of alcohol has never diminished appreciably, although its misuse represents one of the most important sociologic and medical problems. Did the rebellion against the Volstead Act represent a perversity of an ignorant population or did it indicate that, even though a majority of the consumers of alcohol knew its potential toxicity and its personal as well as a social hazard, they were still willing to calculate these risks to be warranted when balanced against personal and social benefits?

There is a tendency to believe, or to lead the public to believe, that the new chemical agents are fundamentally different from those old chemicals with which we have long been in contact. The inference is made that some new principles are needed for handling the problems of toxicity that arise in this advanced chemical age. These new chemicals, however, do not differ in any respect, except possibly in potency, from those with which we are more familiar. Nearly every know chemical substance can produce a toxic action on man if the exposure is adequate. In fact, selective toxicity is the basic principle that governs the activity of the large segment of the chemical industry that deals with the actions of chemicals on biological systems. This principle is basic in the search for a cure for cancer, tuberculosis, or any other disease, as well as in the search for a new insecticide, soil fumigant, or food preservative.

It cannot be denied that sensible laws and regulations are necessary to protect the public against itself and against those unscrupulous persons who would prey on the ignorance or cupidity of individual members of the population. It would appear to be neither dignified nor necessary to use shabby tactics to effect this protection. Yet shortsighted policy, incompetence, bureaucracy, and politics have resulted in such an admixture of fiction with science that it is no longer possible to distinguish truth from propaganda, and vice versa. Numerous technical devices that prohibit rather than aid the determination of the factual state as it relates to toxicity have become established over a period of time; for example, the use of the terms adulteration and standards of identity as virtual synonyms for toxicity has become common administrative practice. Other examples include the use of arbitrary margins of safety without much regard for the conditions of use, transference of toxicity data from its application in one use to an instance in which the data apply to another use, without consideration of the hazard or calculated risk in the latter usage, the denial of established facts based on experience with large groups of human beings if these facts deviate from findings in other animal species, and the use of incompetent witnesses or pseudoscientists to bolster up administrative decisions and influence legislation.

One of the best recent examples of this type of action relates to the decision that bans softeners in bread. These cannot be considered to represent a biological hazard under present conditions of use. That softeners may not offer sufficient material benefit to society to warrant their use is not the point. The real point is how the problem was solved administratively in order to muster support for the decision to discontinue the use of softeners. This was done by declaring the manufacturers guilty of deceptive practices in the name of toxicity because these substances had not been shown to have been nontoxic throughout the whole lifetime of man. If this is perspective, then the scientist had better go out of business.

OUTLOOK FOR FUTURE LEGISLATION

Prolonged adherence to a philosophy of action that places the burden of proof on the administrator, as is the case with foods under the present law, is no easy task especially when capricious decisions are under constant attack. As is inevitably the case when technical progress exceeds human capacity to deal

adequately with a problem, solution is sought in further legislation. Theoretically, this should represent a gain to the state since, in principle, laws are enacted to enable society to retain or regain perspective rather than the converse.

Be that as it may, new legislation is now being considered that will set up a so-called new chemical section of the Federal act that will deal with foods and food products, and will be analogous to that now in use for new drugs. The principal provision of this proposed legislation would be to require proof of the nontoxicity of chemicals in advance of their use. I do not intent to discuss the merits of this new legislation, except to say that I believe that it could be as beneficial as the present new drug section providing it was formulated, enacted, and administered with perspective based on scientific fact. I believe that physicians, who obviously have a vital concern with this problem, should be apprised of the total situation as it now exists, since such new legislation if administered by the existing philosophy would assure a permanently distorted approach to the problem.

In order to effect such legislation, an impartial committee of the House of Representatives to investigate the use of chemicals in food products was impaneled to hold hearings on the problem. In the midst of these hearings, the chairman, James P. Delaney of New York, published an article in the July 1951, issue of the American Magazine. This lurid article, a masterpiece of innuendo and fantasy, based principally on conjecture, was designed for the one purpose of frightening the housewife into demanding further legislation. Mr. Delaney stated: "The Food and Drug Administration has listed 704 chemicals which are being used in our regular food supply, of which only 428 are known to be safe. In other words, 276 chemicals are unknown and untested quantities, and some of them may be slowly poisoning us.

"This potentially lethal situation is due to a curious loophole in our present laws, a tragic legal joker that permits us to become a Nation of 150 million guinea pigs guilelessly testing out chemicals that should have been tested adequately before they reached our kitchen shelves.

"Doctors testifying before the House committee have stated that there may be some connection between these new chemicals and the increase of such diseases as cancer, polio, and the mysterious virus X."

It is interesting to note that laymen also testified before the committee, on medical subjects. Louis Bromfield, novelist and gentleman farmer, testified that virus X, the mysterious, influenzalike epidemic disease, may be nothing more than manifestations of DDT poisoning; and the increased incidence of heart disease, cancer, and leukemia may result from cumulative poisoning by pesticide residues.[3] Evidently, medical evidence from a layman was just as convincing to the House committee as that from the doctors.

Examination of the testimony that was collected with the active backing and support of the regulatory agency involved and was offered before the Delaney committee reveals it to be largely of the caliber just mentioned. For example, nitrogen trichloride (Agene) has been used in the United States for over 25 years to age and bleach flour. A few years ago, it was discovered that this compound produces convulsions in dogs. Although the American people, for 25 years, have been using bread made of flour bleached with this agent, there is no evidence that it has had any deleterious effect on them; yet several self-styled experts, writing in the press and testifying in the Delaney hearing, conjectured or inferred that epilepsy, alcoholism, and a variety of compulsive, convulsive, and excitatory disorders may have resulted from the use of this material for the last 25 years. Millers and bakers voluntarily agreed to abandon its use. I would not object to this action even if legal compulsion had actually been required to enforce it. In this particular instance, the justification for use is so negligible that the calculated risk must be equally negligible. I oppose vigorously, however, the capricious use of these data even to infer toxicity for man. This is more reprehensible since it was designed primarily, if not exclusively, to influence legislation.

If a negative experiment on man involving a 25-year trial in a whole population (possibly 2.5 billion man-years) is ignored as proof of nontoxicity, what conceivable type of evidence could a pharmacologist or a clinician present in advance of distribution in a food product to be utterly and completely without the possibility of human injury?

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[3] Coming: Tougher Food Law, Chemical Week, vol. 69, No. 2 (July 14), 1951, pp. 11–12.

In defense of the competent and experienced scientists associated with these regulatory agencies, let me say that they are often forced by their position to render decisions in the face of innumerable pressures, even though they often lack the definitive information necessary to an adequate decision. This is likely to become worse rather than better. For this reason, some measures should be taken that would permit them to share responsibilities in areas in which they lack competence. Let me cite a few examples of current or future headaches. Chemicals for systemic use that are effective in population control are now available. Can a few administrators with small technical staffs deal adequately with this problem? The problem of carcinogenicity of chemicals stands as an ever present shadow over those responsible for making decisions. There is no possibility of devising experiments on animals that will conclusively guarantee in advance freedom from such an action in man. Are we to deny ourselves the trial use in man of all chemicals because of a possible carcinogenic effect? Chemicals that will alter genetic characteristics in plants, modify their growth, and produce numerous modifications of their biological characteristics have long been known. It is only a matter of further study to find such chemicals that will produce similar effects in man. Probably they will be discovered by accident. In all likelihood, they will not be ascertained in advance. The imagination of the reader may furnish even tougher assignments for the future. Undoubtedly, if most of us were confronted with such problems we would fumble and possibly lose perspective. I hope, however, not to such a degree as to advocate 10-year administration of chemicals to the monkey before admissibility for use in man as was advocated by a well-meaning witness in testimony before the Delaney committee. As one who knows from 25 years' experience how difficult it is to maintain monkey colonies for even a few years, I doubt that the witness has much competence in this area.

CONSIDERATION OF BASIC PRINCIPLES

Is there a better solution to the problem of properly evaluating toxicity of chemicals for man without resorting to the unscientific methods already alluded to? Without offering a categorical answer to this question, it appears timely at least to reconsider what I believe to be certain irrefutable principles upon which evaluation of human toxicity must be based. (1) Every chemical substance has a nontoxic and a toxic dose for man; that is, no chemicals must be poisons, and all chemicals can be poisons. (2) The use of every chemical substance by man, whether it be as a food, drug, cosmetic, insecticide, or for any purpose, is a potential hazard. There are only few exceptions. The risk may be very small or very great, depending on the nature of the chemical, the conditions of use, the degree and duration of exposure, and the condition of the person. (3) The toxicity of chemicals for man can be ultimately determined only by experiments on man. Studies on many species of infrahuman forms can give reasonable assurance that the chemical may be tried in man with a minimal risk, but no set of conditions involving animals alone can prove nontoxicity or toxicity for man. The determination of certain types of potential toxic effects such as genetic changes or carcinogenicity may require several generations or a lifetime of large human populations. It cannot be determined conclusively on any other animal species. On the basis of numerous examples of specific toxic action limited to a single animal species, it is safe to conclude that some day a chemical will appear that is specifically toxic for man alone. (4) The use of every chemical substance in man involves a calculated risk. The degree of risk is calculated by balancing the toxicity of the chemical under conditions of use (its hazards) against its benefits to man, whether these benefits are direct or indirect. Minimal risk is encountered when the dose or extent of exposure is calculated to be tolerated by the weakest member of the population. This would take into account every person who may be specifically sensitive to the chemical. For chemicals designed for internal use or capable of being absorbed into the body, it is impossible to predict with certainty in advance a quantity of the material, or establish a regimen of exposure, or to calculate a margin of safety, which will at the same time assure complete biological effectiveness and absolute nontoxicity in any human population. In other words, the maximal tolerated dose for the weakest member of a population may be ineffective in the most resistant, whereas an effective dose for the latter may be toxic to the former. The common practice of arbitrarily assuming a so-called margin of safety for man, calculated on the basis of data on animals, usually a quantity or concentration tenfold to one-hundred-fold greater than that shown to produce minimal injury in animals,

is at best no more than a means of permitting preliminary experiments in man. At its worst, when used as a substitute for human experience, it arbitrarily eliminates from consideration substances that may be of great practical value. In any event, scientific considerations would demand that such calculations be discarded entirely in the face of human data. (5) The greater the benefit of a chemical substance to man, the greater the justification for the increase in risk in its use. For example, an invariably fatal disease justifies the use of severely toxic compounds. As much as 10 percent expansion of a national food supply by the use of a food preservative or a pesticide would appear to justify a greater degree of risk than that ordinarily permitted in foods in view of the world responsibilities this Nation is being called on to assume. In countries where critical food shortages exist, the individual risk could be very materially increased when it is balanced against national malnutrition and death from starvation.

On the basis of these considerations, we are now, and we will always be, confronted with two distinct and difficult problems, even after the pharmacologist has completed his studies on animals. First, the actual determination of toxicity in man. This requires now, as it will always require, pilot scale use of chemicals in man under controlled conditions in order to ascertain whether full scale use on the whole population may be justified. Such a procedure is inevitably associated with a certain calculated risk. Neither legislation or regulation will alter this fact. The only obvious solution to this problem appears to be "limited use" acceptance until sufficient data in man are collected to arrive at a conclusion. This type of approval obviously could be justified only in the light of careful evaluation of justification for use. The only alternative, from a scientific and medical point of view, is for the public, satisfied with the status quo, to declare a moratorium on further technological advance in the chemical field and individually and collectively to refuse to play the role of Mr. Delaney's "guileless guinea pigs."

The second problem is the determination of justification for use in the light of all the biological and social forces existent in the population. In the latter area, no satisfactory agency or mechanism exists with the composite know-how and vision to deal satisfactorily with this problem, nor does it seem desirable to create such a permanent agency, because each new problem requires a different background in skills and experience for an equitable decision. The real defect in our thinking at the national level has been that, whereas we have created the mechanism for accurately determining toxicity in animals and we know how to determine toxicity in man with a minimal risk, the most difficult facet of this problem, the determination of justification for use, has not been kept in proper focus. It does not seem likely that perspective can be easily gained when any person may assume competence and get a respected hearing without regard to his training, experience, or judgment in these difficult areas, in our lawmaking tribunals.

It would appear that a satisfactory solution to both problems might be gained by the use of ad hoc committees implemented by qualified persons of wide experience and judgment in the principal areas under consideration. Such a technique, while not relieving the regulatory agencies of responsibilities assigned under the law, would have the obvious advantage of at least assuring the public of valid technical as well as moral justification for decisions that might otherwise be made without perspective. Such a commendable plan, operating within the framework of the National Research Council, was utilized most effectively in bringing perspective to a difficult problem dealing with toxicity of one of the antibiotics. Expansion of this technique into other branches of knowledge as they relate to this whole problem of toxicity would appear to be a most worthwhile experiment. Finally, the public should be informed as to the facts. In the final analysis, it is the citizen who would like to assess the calculated risk for himself.

(The following material was received for the record:)

NATIONAL ASSOCIATION OF FROZEN FOOD PACKERS,
Washington, D. C., August 7, 1957.

HON. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, House Interstate and Foreign Commerce Committee, House Office Building, Washington, D. C.

MY DEAR MR. CHAIRMAN: The National Association of Frozen Food Packers respectfully submits the attached statement concerning the proposed food addi-

tive legislation which is now under consideration by the Health and Science Subcommittee.

The association membership is composed of frozen food processors throughout the United States. Its members pack most of the frozen vegetables, juice concentrates, and fruits produced in the United States and a substantial proportion of the prepared frozen foods. The industry has, of course, a substantial interest in legislation which regulates the composition of frozen foods, as does that now proposed.

The association fully supports legislation requiring the pretesting of new food additives to insure their safety and urges the enactment of appropriate legislation for that purpose. We favor, basically, the regulatory approach adopted in H. R. 366 (the declaratory judgment bill) and H. R. 8390 and 8629 (the injunction bills) rather than the licensing approach of the administration bill, H. R. 6747. If, however, the committee should decide to follow the licensing procedure proposed in H. R. 6747, we urge its amendment in certain important respects which are outlined in the accompanying statement.

LAWRENCE S. MARTIN, *Secretary-Manager.*

STATEMENT OF THE NATIONAL ASSOCIATION OF FROZEN FOOD PACKERS ON FOOD ADDITIVE LEGISLATION

This statement will consider certain basic aspects of the pending legislation, using H. R. 6747 and H. R. 8390 as primary points of reference.

THE DEFINITION OF "FOOD ADDITIVE"

H. R. 6747 defines the term "chemical additive" to include any substance which may become a component of or otherwise affect the characteristics of any food, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use.

The first part of the definition found in H. R. 8390, designated "(A)" in the bill, is more precise and understandable than the corresponding portion of the definition in H. R. 6747, and avoids the prolixity of language of H. R. 6747. It seems fully adequate, for this part of the definition, to define an additive as a substance which "(A) becomes or could reasonably be expected to become a component of such food or as used to affect the characteristics of such food," as is done in H. R. 8390.

Part "(B)" of the definition in H. R. 8390 is a simplified version of the "generally recognized" test, which follows basically the definition of new drug in Section 201 (b) of the Food, Drug and Cosmetic Act as enacted in 1938. To that extent it is preferable to the more lengthy and less definitive language of H. R. 6747 on this point.

There is, however, a fundamental defect in both bills, in their resort to the opinions of an undefined group of experts as a basic factor of the definition.

This definition is the fundamental test of whether a substance must be cleared by submission of testing data to the Food and Drug Administration—usually a costly and time-consuming procedure. It is quite evident that, in the case of new additives, the experts will not ordinarily be qualified to pass upon the question of safety, since the new substances or new uses will not be generally known to them. To the extent that they are unknown, such substances cannot be generally recognized as safe.

The effect would be, therefore, that the decision whether a particular substance must be submitted to the Food and Drug Administration for clearance in accordance with the statutory formalities would be arrived at, not upon the basis of the evidence of safety accumulated by the person proposing to use it, but upon the basis of the supposed opinions of a nebulous group of scientists or other experts. Thus, the merits of the qeustion of safety need not be reached in determining whether an additive is subject to the legislation. In the event of litigation on this jurisdictional question, the inquiry of the court would be directed basically to the question of whether the experts generally recognized the additive as safe, rather than to the adequacy of actual experimental evidence of safety developed by industry.

We believe that there should be a decision upon the facts by the Food and Drug Administration in determining jurisdiction under this far-reaching legis-

lation, not simply a recourse to the frequently illusory test of general recognition by experts.

We hope that a realistic evidentiary basis for such determinations will be considered by your committee. It might reasonably be provided that the term "food additive" includes any substance which may become a component of food unless there is clear and convincing evidence upon the whole record that its use under the intended conditions will offer no reasonable possibility of hazard to the public health. Thus, if the pretesting evidence submitted by the proponent of an additive is clear and convincing on the question of safety, there would be no valid reason to burden the proponent with the clearance procedures which will be instituted by the Food and Drug Administration any more than such a burden should be imposed if it could be determined that the additive was generally recognized by the experts as safe.

It is submitted that industry should not be required to submit to the proposed clearance procedures and, perhaps, to undertake extensive studies of the toxicological and pharmacological characteristics of a new additive, where there exists clear and convincing evidence of its safety, solely because the additive or its intended use is not generally known to the experts and, therefore, could not be generally recognized by them as safe. Under such circumstances, if the Food and Drug Administration should insist upon such studies, the proponent could determine the course to follow with the knowledge that, should the Administration bring legal action against him, the question of jurisdiction would be determined upon the basis of a real evidentiary test. Yet the public interest would be protected by the requirement of clear and convincing evidence that the additive had been adequately tested for safety as a condition of exemption from the definition of food additive.

These suggestions do not relate to the matter of appellate review of agency determinations of the safety of substances which are formally submitted for clearance under the proposed legislation. It concerns only the question of "what is an additive"—whether a substance used in food must be submitted for clearance. Judicial review of decisions with respect to substances which have been formally submitted for official clearance is considered hereinafter.

We urge also the adoption of a "grandfather clause" which will adequately recognize the position of additives in use on the effective date of the legislation, for which no "sanction or approval," within the meaning of H. R. 6747 has been granted under the Food, Drug, and Cosmetic Act or the Meat Inspection Act.

It has been suggested to the subcommittee that such additives should continue to be policed under the old law unless and until a regulation respecting their use is issued under the new legislation. This appears to be a reasonable solution to the problem, if provision is made giving the proponent of continued use a reasonable opportunity to comply with the requirements of the new law. We suggest that a further provision be added requiring the filing with the Food and Drug Administration of the names and chemical composition of such old additives, as a condition of their continued use pending the issuance of a regulation. In this manner the Food and Drug Administration would be apprised of the nature of the old additives in use and would be in a position to take appropriate action under the old law with respect to any which were considered to be unsafe. Of course, no substance would be subject to the filing requirement which was not included within the definition of "food additive" adopted by the Congress.

The term "food additive" is used in these comments, rather than "chemical additive." It more aptly describes the broad range of substances which would be affected by the proposed legislation and should, we suggest, be employed in the law.

FUNCTIONAL VALUE OF ADDITIVES

Unlike H. R. 366 and H. R. 8390, the administration bill would permit the Food and Drug Administration to take the functional value of an additive into account in considering its proposed use, unless it should find that the additive was not a poisonous or deleterious substance.

Under this provision of the administration bill, an additive could be rejected solely upon the ground that functional value had not been demonstrated to the satisfaction of the Food and Drug Administration, without regard to whether the additive met the criteria of safety established by the statute.

We join with other segments of the food industry in fundamental opposition to provisions which would permit the Food and Drug Administration to determine the composition of food products upon the basis of its conception of functional value or utility of food ingredients. In the case of poisonous or

deleterious ingredients, the likelihood of a food processor undertaking the expense of pretesting for safety of an ingredient without functional value seems rather remote. In any event, the question of usefulness of an ingredient shown to be safe is one which the manufacturer of the food is entitled to resolve upon the basis of his own experience, and is not properly a matter for the opinion of the Food and Drug Administration.

If the processor should make misrepresentations to the public with respect to the value of an additive, he would be subject to proceedings under the Federal Trade Commission Act (which contains specific provisions prohibiting the false advertisement of foods) or under the existing misbranding provisions of the Food, Drug, and Cosmetic Act.

STATUTORY REVIEW PROCEEDINGS

We believe that the control which would be granted to the courts over administrative determinations under H. R. 366 (actions for declaratory judgments) and H. R. 8390 (suits by the Government for injunctions against the use of additives) are more appropriate to legislation of the vast scope and importance of that under consideration than review by the United States courts of appeals, as proposed in H. R. 6747. The reasons for this view have been placed before the subcommittee by other representatives of the food industry.

If, however, review by the courts of appeals is decided upon, we earnestly request that the scope of review contemplated by H. R. 6747 be broadened sufficiently to afford a real and effective judicial consideration of administrative determinations. This is not obtainable, as a general matter, under the administration bill, which requires affirmance of Food and Drug findings if they are supported by substantial evidence upon the whole record.

The situation would rarely arise where the administrative findings could be set aside because of the lack of substantial evidence. On the other hand, if the reviewing court were permitted to set aside findings which were clearly erroneous because they were against the clear weight of the evidence, a court's conviction that the agency's determination was wrong could be translated into positive action to protect the rights of litigants.

Rule 52 of the Federal Rules of Civil Procedure permits an appellate court, in nonjury cases, to set aside the findings of the trial court if they are "clearly erroneous." Former Attorney General William D. Mitchell, Chairman of the Advisory Committee appointed by the Supreme Court to draft the Federal Rules, stated that "in the present practice on the equity side [from which the clearly erroneous rule was derived] where the findings are made by the judge without a jury, on appeal, those findings may be examined and the evidence may be examined," and that the "clearly erroneous" rule permits the appellate court to consider the weight of conflicting evidence and to reverse on the ground that the finding is "against the clear weight of the evidence." [1]

The effect of writing the "clearly erroneous" rule into food-additive legislation could be made definite by adding a provision defining the term "clearly erroneous" to mean "against the clear weight of the evidence upon the record considered as a whole."

With such provisions, the reviewing court would be in a position to give proper weight, not only to evidence introduced in an administrative hearing by the Food and Drug Administration, but, also, to that presented by industry.

The proposed Code of Administrative Procedure of the American Bar Association would include within the scope of court review, in cases of adjudication, the question of whether the findings of the administrative agency are "clearly erroneous on the whole record" (sec. 1009 (f)). The provisions for court review herein proposed for consideration would be consistent with those of the proposed Code of Administrative Procedure. They would simply go further and define the term "clearly erroneous" to mean "against the clear weight of the evidence," as it was explained by former Attorney General Mitchell.

The vast authority over the food supply proposed in the administration bill seems clearly to justify that an adequate review function be vested in the courts, without regard to whether that function is of the same scope as that under other provisions of the Food, Drug, and Cosmetic Act. The kind of provision proposed

[1] Mr. Mitchell's remarks are taken from proceedings of the Institute on Federal Rules (Cleveland, Ohio) and proceedings of the symposium at New York. They are quoted in Stern, Review of Findings of Administrators, Judges, and Juries: A Comparative Analysis, 58 Harvard Law Review 70, at pp. 84–86.

would not be an untested one, since it exists in current court practice and is, in essence, codified under the Federal Rules of Civil Procedure.

We appreciate the opportunity of submitting this statement on behalf of the frozen-food industry.

WASHINGTON, D. C., *August 5, 1957.*

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D. C.

DEAR SIR: This statement is submitted on behalf of the Waxed Paper Institute, Inc., for inclusion in the record of the hearings, which began on July 15, 1957, on the food-additive proposals. The institute is a trade association made up of 23 waxed-paper converters or manufacturers.

The institute wishes to go on record, first, as approving the principle of requiring that additives be adequately tested before they may be used in foods to be sold to the general public. Its members also feel that the primary responsibility for that testing belongs with industry, not the Government. They do not feel, however, that legislation to protect the public need put an intolerable burden on industry, or that it need go so far as to stifle the development of new additives.

Secondly, the institute asks that packaging materials be exempted entirely from any legislation that may be passed. Those materials cannot be said to be "food additives," and they contain nothing that is deliberately intended to become a part of foods. Furthermore, the possibility that packaging components will become integrated with food is remote. There have, so far as we know, been no instances of a food's being contaminated so as to be injurious to health by the migration of packaging components into the food. The evil sought to be cured by including packaging materials in food additive legislation is, therefore, very slight.

Needless to say, no member of the waxed-paper industry, and, doubtless, no member of any other packaging industry, puts new materials on the market until it is satisfied that the materials can be used with safety. A manufacturer of packing materials, however, has no control over the ways in which the materials are stored, the products on which they are to be used, the manner in which they will be handled after foods are wrapped in them. To hold a manufacturer of packaging materials responsible for anticipating the many possible uses to which his products may be put, and for determining whether or not any component of the material might become a harmful part of food under each possible use, would place too heavy a burden on the manufacturers of such materials. It could effectively discourage the development of new and improved packaging materials, particularly by smaller companies.

We may point out here that packaging materials are designed to, and do, protect foods from contamination. Improvements and new developments in the industries in recent years have been phenomenal. These developments have not been accompanied by any deleterious effects upon foods, but it is doubtful that the advancements would have come about if the pretesting requirements of some of the measures now before the subcommittee had been in effect.

If the subcommittee will not exclude packaging materials entirely from food-additive legislation, the Waxed Paper Institute recommends the approach taken by Congressman Miller in his bill, H. R. 8112. Packaging materials are included in that part of the bill, section 2 (t), which defines an "incidental food additive." The term is said to mean "any substance intended for use in manufacturing, packing, processing, preparing, treating, packaging, or transporting food *which foreseeably results*, in the course of good manufacturing practice, in its getting into the food." [Emphasis supplied.] Thus, not all additives used in packaging materials would fall under the legislation. Only those that could be expected to migrate into the food would be subject to it.

H. R. 8112 also lightens the pretesting requirements as they would apply to the components of packaging materials. For those components that might be expected to become a part of food pretesting would have "to show whether or not such incidental food additive migrates into food in a quantity which is toxicologically significant from the standpoint of the protection of public health." If the Secretary of Health, Education, and Welfare did not issue an order within 90 days after the submission of the pretesting evidence, the substance might be used. This provision is more lenient than that which would apply to real food additives under H. R. 8112.

We need not state fully our views on other aspects of the measures now before the subcommittee. To do so would repeat much that has been said at the hearings. In general, however, members of the institute wish to express the following views on several aspects of the food additive proposals:

They are in favor of exempting from pretesting requirements those additives that have been in use for a sufficiently long period of time for their safety to be established, and they ask that legislation provide for the recognition of informal rulings issued by the Food and Drug Administration in the past on the use of additives.

They oppose the licensing principle of section 5 of H. R. 6747, the Food and Drug Administration's proposal, which would give the FDA virtually absolute authority over the use of new additives.

They oppose any requirement that an additive must be shown to serve a useful purpose or have functional value before its use may be approved by the FDA.

They oppose any provision for reference of pretesting data to an advisory committee, as is incorporated in H. R. 6747, made up of disinterested scientists appointed by the FDA.

They support the idea that an additive should be considered safe for use when it has been shown that the substance, as it is to be used, is "without hazard to human health."

They support the requirement that the FDA's orders regarding additives be published in the Federal Register, so the other manufacturers may know of the order and may use the additive if it is not patented.

Respectfully yours,

GEORGE P. LAMB,
General Counsel, Waxed Paper Institute, Inc.

BOYCE THOMPSON INSTITUTE FOR PLANT RESEARCH, INC.,
Yonkers, N. Y., July 30, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Health and Science Subcommittee, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D. C.

DEAR MR. WILLIAMS: I wish to comment on the hearings now in progress on the various food additive bills (H. R. 366, 6747, 7700, 7798, 7938, 8112, and 8390).

It seems to me that we may be falling into a position where we will retrace our steps, to no constructive or worthwhile purpose, over the ground covered in the Delaney hearings, and in the Food and Drug Administration hearings that preceded passage of the Miller bill that was enacted into Public Law 518 by the 83d Congress.

There is a distinct and functional difference between the intention additives (added to enhance flavor, processing, esthetic value, retention of usable life, etc.) and the incidental additives that inadvertently occur in food because of their indispensability in production or processing of the crop. The former can be omitted if there is any evidence of mammalian toxicity while traces of the latter cannot be avoided and the concentration must be maintained at such a low level that their presence will not present undue hazard to the consumer. Members of neither class should be permitted in commercial use before their toxicity has been fully assayed and maximal tolerances have been established by competent authorities. These basic concepts were evolved in the deliberations of the food protection committee in 1951 and were considered indispensable to a rational study of the problem.

The pesticides were given their day in court in the period 1950–53. Every aspect of their use and commercial development was studied by industrial groups, health agencies, professional societies and associations and independent agencies such as the National Research Conucil's committee on food protection. The opinions of spokesmen for these groups and of both competent and incompetent individuals were taken in the records of our Congress. The incidental additives were maligned and the dangers from their use distorted by many faddists, but it is to the enduring credit of our legislators that they placed these comments in proper perspective and developed a sensible, workable procedure for protecting our food supplies.

Public Law 518 has just begun to function properly and is proving exceptionally effective. It does demand such expensive toxicity and residue data that a

heavy burden is placed on those who do research but this seems an inescapable necessity against which no rational person would argue. For the first time we now have a workable procedure for protecting our food from incidental additives that has no loopholes to permit careless introduction of new products, where tolerances may be established soundly, and a mechanism for resolving differences in interpretation of technical data on residues and toxicology has been developed.

It seems to me that a pattern has been established for regulating the intentional additives. However, there is no good reason why the current hearings should be allowed to mushroom out into the pesticide and other incidental additive fields. This would merely create confusion and further discourage progress in preventing both the loss of crop and reduction of food quality by pests. These pests destroy productivity equivalent to 88 million acres (21 percent of our crop) and the time has come to concentrate upon their control rather than to keep industry on the defensive. This industry is fully regulated in the interest of public safety and deserves a chance to prove its worth under the new laws we now have in operation. May I suggest, therefore, that the present hearings concentrate on the area where legislation has not been revised and modernized.

Sincerely yours,

GEORGE L. MCNEW, *Managing Director.*

UNIVERSITY OF PENNSYLVANIA,
THE GRADUATE SCHOOL OF MEDICINE,
Philadelphia, May 31, 1957.

Hon. JOHN B. WILLIAMS,
Chairman, Subcommittee on Health and Science,
House Office Building, Washington, D. C.

DEAR MR. WILLIAMS: I write urging your support for the Delaney bill (H. R. 4014) to assure safety of chemicals in foods. It is urged that you and your colleagues take all necessary steps to amend the Delaney bill, and other food additive bills, and the Miller Pesticide Act:

(*a*) To specify that chemicals used in or on food be tested for carcinogenicity (ability to induce cancer).

(*b*) To specify that approval for use of chemicals in or on food be restricted to a limited list of selected substances for which the Secretary of the Department of Health, Education, and Welfare finds there is actual need and adequate evidence of safety, provided the Secretary shall not approve for such use any substance which he finds can induce cancer.

Need for these amendments arises from provisions permitting use in food of safe quantities of chemicals found harmful in higher concentration.

Resolutions adopted by the International Union Against Cancer point out that safe doses cannot be established with confidence for chemicals that induce cancer (carcinogens). These have long-delayed action. Single doses eaten by young test animals resulted in cancer late in life.

Those who have studied this problem feel that the language of amendment (*b*) above affords adequate provision for necessary chemicals. It affords the Secretary opportunity to exercise judgment in evaluation of claims for carcinogenicity.

It is hoped that you and your committee will support the stand taken by the International Union Against Cancer.

Very truly yours,

H. L. BOCKUS.

HOUSE OF REPRESENTATIVES,
Washington, D. C., June 5, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D. C.

DEAR MR. WILLIAMS: On May 28, 1957, I introduced H. R. 7798, to replace my former chemical additive bill, H. R. 4014. H. R. 7798 is identical with H. R. 4014, except for the few but important additions noted in the enclosed memorandum.

I included the anticarcinogen provisions in H. R. 7798 as the result of further correspondence with Dr. William E. Smith, to whom I referred in my testimony at the sponsor's hearing of my earlier bill, Dr. Francis E. Ray, director of the cancer research laboratory of the University of Florida, who was one of the

American representatives at the cancer symposium in Rome last summer, and other medical authorities. It may be noted that these provisions are in accordance with the recommendations made by the cancer symposium.

The enclosed letter from Dr. Ray was not received in time for me to introduce it at the sponsor's hearing for H. R. 4014. If it is possible to have it included in the record of the hearing, I would appreciate it, since I feel that the committee should have the benefit of the expert views expressed.

If the additional provisions contained in H. R. 7798 require that any additional reports be obtained, I respectfully ask that the committee request them.

Very sincerely,

JAMES J. DELANEY,
Member of Congress.

THE J. HILLIS MILLER HEALTH CENTER,
CANCER RESEARCH LABORATORY,
UNIVERSITY OF FLORIDA,
Gainesville, March 26, 1957.

Hon. JAMES J. DELANEY,
House Office Building,
Washington, D. C.

DEAR CONGRESSMAN DELANEY: I would like to call your attention to some of the recommendations of the 1956 Rome Symposium on Potential Cancer Hazards from chemical additives and contaminants to foodstuffs:

"1. Food additives should be permitted only if, after long-term administration to at least 2 species of animals (1 preferably a nonrodent) orally or parenterally, in amounts which must be considerably higher than would be present in food, so as to give adequate margin of safety and, after observation of the animals over their lifetime, and through at least 2 generations in at least 1 suitable species, they have no toxic effect.

"2. Any substance which causes cancer in man or which, when tested under these conditions, is shown conclusively to be a carcinogen *at any dosage level, for any species of animal, following administration by any route,* should not be considered innocuous for human consumption."

The reason for the words italicized is that no animal is exactly like man in its response to drugs and poisons, but substances that cause cancer in man almost invariably cause cancer in some species of animal by some route of administration.

Let me illustrate this: Beta napthylamine produces cancer of the bladder in man but not in rats, mice, or rabbits. It does, however, produce bladder cancer in dogs. Again, methylcholanthrene when painted on mice readily produces tumors. Rats, on the other hand are quite resistant to methylcholanthrene skin cancer.

As to the mode of administration: Adenocarcinoma (cancer) of the stomach is one of the most malignant forms of cancer to attack man. Yet it is doubtful if any case of adenocarcinoma of the stomach has ever been found in an animal. Feeding carcinogens does not cause this form of cancer in animals. Any substance, therefore, that could cause gastric cancer in man would not give a test for gastric cancer if fed to an animal.

Such a substance would be very much more apt to produce skin cancer when painted on mice or sarcomas when injected into the muscle of rats or hamsters. Because of these species differences we must, in order to maintain a factor of safety, conclude that any substance that causes cancer in any animal by any route of administration must be rejected as food additive. I would like to emphasize that there is no safe dose of a cancer producing chemical.

I hope it will be possible to pass legislation that will adequately protect the public. I think your bill is the best fitted to do this, but should specifically exclude carcinogens as food additives.

Yours sincerely,

FRANCIS E. RAY, *Director.*

CHANGES MADE IN H. R. 4014, NEW BILL H. R. 7798

On the first page, line 9, after the word "food", insert a comma and the following: "including any radioactive material intended for any such use".

Page 2, line 1, insert after the word "food", the following: "including any radioactive material intended for any such use".

Page 3, line 16, after the word "toxicity" insert a comma and the following: "carcinogenicity,".

Page 5, line 14, strike out the period and insert in lieu thereof a comma and the following: "including any hazard to the health of the consumer from food which is yielded by, or derived from, any animal or plant into which such chemical additive has been introduced by feeding or otherwise. The Secretary shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals."

NEW YORK, N. Y., *August 9, 1957.*

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House Office Building, Washington, D. C.

DEAR MR. HARRIS: This letter is written from the Palace Hotel, Burgenstock, Switzerland, and copies have been mailed to Mr. Williams and all other members of your committee and to the able committee counsel, Mr. Borchardt.

(1) Re international conference in London on July 26 to discuss control of chemical additives in food, which I chaired: This conference was cosponsored by my Food Law Institute and the major British societies on food science; the United Kingdom Ministry of Food participated in it; and it was held in the Royal Scientific Institution. Papers were recorded by the highest food law officials and scientists in the United States, Canada, and Great Britain; which discussed every basic phase of the subject. For this reason the conference was an historic one of great educational value; and its proceedings will be published in the August issue of our Food-Drug-Cosmetic Law Journal. The attendance exceeded 400 and also included numerous food industry lawyers from the United States and food scientists from throughout England, Scotland, and Wales and from Western Continental Europe. At the end it was decided to hold supplemental international conferences in London on the food law, because of their educational value; and to organize a special conference there in 1960 to commemorate the 100th anniversary of the original English pure food law. (It is parenthetically added that the Inter-American Bar Association will have a pioneer food and drug law meeting at Buenos Aires in November, which I will address.)

The general conclusions reached at this conference were substantially these: First, chemical additives have an essential role in the modern manufacture of foods, to preserve and improve them; but, secondly, the national pure food law should assure their safe use, by a pretesting requirement, etc., where it scientifically applies. And they are precisely the conclusions reached in my July 15 statement to your committee, for a food additive amendment of our Federal Food, Drug, and Cosmetic Act, which was made for the overall national association of leading food manufacturers of every kind, in our country.

(2) While in Europe I have received the transcript of the July hearings before Mr. Williams' subcommittee, on this amendment. They confirm what my statement recommended. It is that the FDC Act should be amended to enact such a pretesting requirement for food additives, except as duly provided; and that the committee should resolve the FDA-industry issue over the form of this amendment, on a sound and just compromise basis. The plainly indicated compromise is what my statement suggested, namely, to take the administration bill for this amendment (H. R. 6747) and thoroughly revise it to settle that issue. I explained our recommended revision in full detail, but I now add the following qualification. The revised bill should omit any provision for a de novo trial review of an administrative regulation against a food additive, by the United States district court. This for the reasons argued by Judge Biggs and the FDA and summarized in the last part of my statement. For the food industry should be sufficiently protected against a misadministration of this amendment by (*a*) the right of scientific review permitted by H. R. 6747 and made to conform with the Administrative Procedure Act policy, on which right we insist; (*b*) revising the administrative review provided by that bill, to assure independent and impartial hearing examiners as required by the above act; and (*c*) revising the appeals court review provided by that bill, to make the administrative findings of fact conclusive only where supported by the weight of the evidence as is now done in the Commodity Exchange Act. I add that the problem of the "generally recognized" rule in the definition of a food additive could be fairly solved by substituting an "adequately recognized" rule.

I shall return to New York early in September and I will thereafter be at the advisory service of your committee, if and when this is desired. A copy of this letter also goes to Commissioner Larrick.

Sincerely yours,

CHARLES WESLEY DUNN.

ELI LILLY & Co.,
Indianapolis, August 9, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science,
House Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D. C.

MY DEAR MR. WILLIAMS: During the current hearings of your subcommittee on proposed legislation to regulate the addition of chemicals to foods, it has come to our attention that the safety of the use of diethylstilbestrol, either by implantation or by addition to feed supplements, has been discussed. According to our information, the question was first raised on July 24, 1957, in the testimony of Dr. W. Coda Martin, president of the Academy of Nutrition, and was again discussed during the scientific panel presentation on August 7, 1957.

While we believe that the total evidence before your subcommittee at this time compels the conclusion that no hazard to health is created by the currently controlled practices of using diethylstilbestrol in the fattening of beef and poultry, nevertheless, as the manufacturer of "Stilbosol," a premix containing diethylstilbestrol utilized by feed manufacturers for incorporation in cattle feed supplements under clearly defined procedures established by the Food and Drug Administration, we feel that the following additional information should be considered by your subcommittee.

1. In connection with the testimony of Dr. Martin the paper entitled "Possible Cancer Hazard Presented by Feeding Diethylstilbestrol to Cattle" was made a part of the record. This paper, prepared by Granville F. Knight, W. Coda Martin, Rigoberto Iglesias, and William E. Smith, was presented by Dr. William E. Smith at the Symposium on Medicated Feeds held in Washington on January 23 and 24, 1956, and following the presentation of the paper, the conclusions of the authors were discussed and criticized in the course of a panel discussion. In order that your subcommittee may consider not only the paper presented by Dr. William E. Smith but likewise the views and conclusions brought out during the panel discussion of the paper, we are enclosing a reprint of the paper and of the panel discussion with the request that the printed discussion be made a part of the record of the hearings immediately following the inclusion of the paper.

2. The practice of using diethylstilbestrol pellets, by implantation, in the fattening of poultry was considered quite extensively by the Delaney committee. We refer particularly to the testimony of Don Carlos Hines, M. D., appearing on pages 1418–1461 of the printed hearings before the Delaney committee, 82d Congress, 2d session, part 3, pursuant to House Resolution 74 and House Resolution 447. We suggest that this testimony be reviewed by members of your subcommittee and that you incorporate it as a part of the record of the hearings before your subcommittee if you deem it appropriate to do so.

3. Reference is made to an article appearing on page 1473 of the July 27, 1957, issue of the Journal of the American Medical Association entitled "Estrogen Residues in Meat—Public Health Aspects" by George M. Briggs, Ph. D., Bethesda, Md., from the Laboratory of Nutrition and Endocrinology, National Institutes of Health, Public Health Service, United States Department of Health, Education, and Welfare.

All of the material referred to above proves conclusively that the public health is not endangered by the inclusion of diethylstilbestrol in feed supplements for the fattening of cattle in accordance with the procedures approved by the Food and Drug Administration.

If either you or any member of your subcommittee desires any further information on this question we will make every effort to furnish it to you promptly.

We request that this letter be made a part of the record of the hearings.

Very truly yours,

W. M. WHEELER, Jr.

ATLAS POWDER CO.,
Wilmington, Del., August 19, 1957.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, House Committee on Interstate and Foreign Commerce, House Office Building, Washington, D. C.

DEAR CONGRESSMAN WILLIAMS: During the course of your subcommittee's hearings on food additives, repeated reference has been made to the *Atlas Powder Co.* v. *Ewing* case and to the (Federal Security) Administrator's alleged findings that the emulsifier involved was "not safe."

The characterization "not safe" was employed specifically in the colloquy between Representative John W. Heselton and Dr. R. Blackwell Smith on July 16, 1957, and also by Chief Judge John Biggs, Jr., during his questioning by the subcommittee on July 22, 1957.

In order that the record be clear and complete on this point, we should like respectfully to point out that neither the Food and Drug Administration nor the then Federal Security Agency had ever described the product as "not safe."

In both the tentative bread order (issued August 8, 1950) and in the final order (promulgated May 15, 1952), the Administrator conceded that there was "no definite evidence of injury" from the use of the emulsifier in bread. This finding was acknowledged and recognized by the United States Third Circuit Court of Appeals in its opinion of December 22, 1952.

It should be thoroughly understood that the issue before the court was not whether the emulsifier was "safe" or "not safe." The ruling turned mainly on this question: Whether, in the absence of evidence showing deleterious effects, the Administrator was correct in finding that the tests in the bread record had not fully established the safety of the product for continuous use over the human life span? On this point the court upheld the Administrator.

While the bread hearings produced disagreement among scientific experts, we believe it important for the record to show that no responsible authority has ever demonstrated any harm to consumers arising from the use of any Atlas emulsifier. In the interest of fairness to all concerned, we request that this communication be inserted at an appropriate place in the subcommittee hearings.

Sincerely,

RALPH K. GOTTSHALL.

DRUG, CHEMICAL, AND ALLIED TRADES SECTION,
NEW YORK BOARD OF TRADE, INC.,
New York, N. Y., July 29, 1957.

Re H. R. 6747 and other bills concerning food additives.

Hon. JOHN BELL WILLIAMS,
Chairman, Health and Science Subcommittee, House Interstate and Foreign Commerce Committee, Washington, D. C.

DEAR SIR: The drug, chemical and allied trades section of the New York Board of Trade is composed of over 800 members representing a cross section of the drug and chemical industry throughout the United States. It has during the past few years, followed closely legislation introduced pertaining to so-called food additives and has taken occasion to record the feeling of its membership in respect to them.

Because of the widespread interest of our members and the fact that many of them are vitally interested in the proposed legislation, we filed a brief statement with the Committee on Interstate and Foreign Commerce in Feburary of 1956 and we wish at this time to reiterate the views already expressed and as briefly as possible to expand upon them.

The drug and chemical section is not unsympathetic to the general principle that before a new additive is included in a food product, some independent check of the manufacturer's tests should be undertaken and we agree that the Federal Food and Drug Administration is a qualified agency.

Most of these bills, including H. R. 6747, as you are well aware, are patterned generally upon the principles of section 505 of the Federal Food, Drug, and Cosmetic Act which requires the submission of all data in respect to a new drug to the Food and Drug Administration and an application permitted to become effective by such Administration, before any such new drug may be distributed in interstate commerce.

Our section believes that the evaluation of the pretesting of new additives by a governmental agency undoubtedly is the public interest, notwithstanding the fact that experience has not disclosed, from a scientific standpoint, any important lack of compliance in respect to the so-called food additives now required under the far-reaching provisions of the present Federal Food, Drug, and Cosmetic Act.

We are, however, concerned with the problem which is involved in the proposed food-additive legislation because of the extreme responsibility which would be placed upon a Federal agency for what, in effect, would be an approval of a new food ingredient. We cite the experience both of the Food and Drug Administration and industry in respect to the delays which no doubt necessarily have occurred in action upon applications covering new drugs under section 505 of the Federal Food and Drug Act. In the case of drugs, we generally are dealing with products which are taken temporarily to meet specific disease conditions and obviously, their potentialities are weighed against the ultimate good which may be obtained.

The bills in question deal with an entirely different condition since the additives will be included as ingredients in foods which may, and in many cases will, be ingested each day over a long period of years. We naturally have some concern that progress in the development of useful products may be hampered unless the legislation resulting from the several bills under consideration does not provide for speedy determination of the reasonably foreseeable questions.

In view of the fact that we are dealing in these bills with substances that may be taken in varied amounts over varying periods of time, we strongly urge that any standards for their evaluation take into consideration all the circumstances.

In other words, we do not favor the rigid application of the so-called per se doctrine if evaluation of the evidence submitted by the manufacturer shows that under the circumstances of use the product is safe on the basis of the available scientific information.

For those reasons, we believe, as a fundamental principle, any law that is enacted should provide for complete disclosure of all data accumulated by the manufacturer to the Food and Drug Administration with the further provision that if, after consideration of such data for a reasonable period, the Food and Drug Administration does not feel justified in permitting the sale of the product, it shall have the right to seek an injunction and thus permit the matter to be settled in the court.

We further submit that any law concerning the so-called food additives which is enacted should contain no reference to the effectiveness or usefulness of the product in question since, obviously, that is a matter for determination by the manufacturer and in the long run will be settled by the practical results.

We should also like to emphasize that we are strongly opposed to the provision in any food additive law which would subject to it those food additives which are freely sold and in use prior to the enactment of such law.

In other words, we favor a so-called grandfather clause which would exempt those products already on the market on the effective date of any such legislation and, conversely, we do not believe any such law should apply to existing food additives since that would cast an unreasonable burden upon manufacturers and possibly disrupt many normal existing trade channels. We feel strongly on this point since any such additives have, since the enactment of the 1938 Federal Food, Drug and Cosmetic Act, been subject to the stringent requirements of that law.

These mainly are the broad principles which we believe should be considered in any such far-reaching legislation as that proposed in the above bills.

We shall appreciate your consideration of this submission and its inclusion in the records of the hearings held in respect to them.

Respectfully yours,

J. DAVID HAYDEN, *Chairman.*

AMERICAN FARM BUREAU FEDERATION,
Washington, D. C., August 14, 1957.

Hon. JOHN B. WILLIAMS,
House of Representatives,
Washington, D. C.

DEAR CONGRESSMAN WILLIAMS: The American Farm Bureau Federation favors the enactment of legislation to establish safeguards against the use of unsafe additives in food.

Farmers, who are the primary producers of food, want their products to reach consumers in a safe and wholesome condition. They also want consumers to have a justified confidence in the safety and wholesomeness of our national food supply.

With the advance of food technology a large number of new substances constantly are being developed for use in processing, preparation, and preserving of food. Many of these food additives perform valuable functions, but farmers and the general public have a right to insist that safeguards be established against the use of unsafe substances in food. It is our understanding and belief that most food processors agree with this view.

The following principles relative to the use of food additives were adopted by our board of directors in 1953 and reaffirmed as recently as June of this year:

I. We believe it is the responsibility of food producers and processors to exert every effort toward the production and distribution of foods which are wholesome and nutritious and to assure adequate safeguards against contamination or adulteration which would render human food unwholesome.

II. We believe food producers and processors should continue to improve their food products from the standpoint of nutritive value, wholesomeness, palatability, and convenience, and that public health and welfare should continue to be the first consideration in such efforts.

III. We believe every substance not proved safe by long usage in human diet should be subject to question as an ingredient in food, and that this question should be resolved by adequate animal experimentation.

IV. We believe every new substance proposed for use in human food should be subjected to adequate pretesting by the manufacturer or commercial user and that such pretesting should be required by law.

V. We believe, further, that the law should require that the results of animal experimentation in pretesting new substances proposed for use in food shall be reviewed and approved by the appropriate qualified Government agency with proper provision for appeal, review, and adjudication before the substance is allowed to be used in food sold to the public.

In conclusion, we believe that legislation should be enacted without delay to require adequate pretesting of new food additives; approval of such substances by the appropriate Government agency prior to their use; and an appropriate appeals procedure. We do not have a position of the fine points of the controversy that apparently exists in some quarters with regard to procedure that should be followed in case of appeal. We do, however, feel that it would be unfortunate for Congress to allow a dispute over legal technicalities to result in the undue delay of legislation that appears to be needed to protect the public welfare.

We would appreciate having this letter included in the record of the hearings that your subcommittee has been holding on this subject.

Sincerely yours,

JOHN C. DATT,
Assistant Legislative Director.

FOOD ADDITIVES

TUESDAY, APRIL 15, 1958

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND SCIENCE OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met, pursuant to notice, at 10 a. m., in room 1334, New House Office Building, Hon. John Bell Williams, chairman of the subcommittee, presiding.

Mr. WILLIAMS. The committee will be in order.

This morning the Subcommittee on Health and Science starts what we hope will be the final round of hearings on chemical additive legislation. We have quite a number of bills before the committee and in the announcement of the subcommittee in which those bills are listed, I noticed that one is left out, the bill which I introduced recently, H. R. 10404. For the benefit of those present I might state that this bill was introduced by request of one segment of the industry merely in order to get it before the committee for consideration and is not intended as my own personal answer to the chemical additive problem.

(The text of H. R. 10404 appears on p. 532.)

The subcommittee held extensive hearings on this subject in July and August of last year. For 2 days the subcommittee was privileged to hear the testimony of a panel of experts on the subject of chemical additives.

Today and tomorrow we expect to hear from witnesses representing the Food and Drug Administration and the Department of Health, Education, and Welfare, and from some industry witnesses who have expressed an interest in testifying briefly on these bills.

A number of years have passed since the House of Representatives created a select committee under the chairmanship of Congressman Delaney to investigate the use of chemicals in food and cosmetics. The select committee filed its report during the 82d Congress, and credit is due the committee and its able chairman for focusing interest in Congress and throughout the Nation on the problem of chemicals in food.

Since then numerous bills have been introduced which prove one important fact, and perhaps the only fact these hearings have proven so far—that there is a basic agreement among all concerned that chemical additive legislation is needed.

As I said in my opening statement, a 10-year period is a sufficiently long incubation period even for difficult legislation—and it is my sincere hope that during the present session, chemical additive legislation which protects the public interest and which meets the needs of our

chemical and food industries will finally be placed on our statute books.

This morning our first witness is Hon. Elliot L. Richardson, Assistant Secretary of the Department of Health, Education, and Welfare.

Mr. Richardson, I believe you have a prepared statement which you would like to submit to this committee before the members interrogate you.

STATEMENT OF HON. ELLIOT L. RICHARDSON, ASSISTANT SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY THEODORE ELLENBOGEN, LEGISLATIVE ATTORNEY; HON. GEORGE P. LARRICK, COMMISSIONER, FOOD AND DRUG ADMINISTRATION; AND JOHN L. HARVEY, DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Mr. RICHARDSON. Thank you, Mr. Chairman. I do have a statement which I would like to read.

My name is Elliot L. Richardson. I am Assistant Secretary for Legislation of the Department of Health, Education, and Welfare. On my left is Commissioner of Food and Drug George P. Larrick and Deputy Commissioner Harvey, and on my right, Mr. Theodore Ellenbogen, legislative attorney in the Office of General Counsel of the Department.

I would like Mr. Chairman, to emphasize particularly the procedural aspects of the legislation before the subcommittee, and in that connection it may be of help to the committee if I very briefly summarize my own background so far as it may to any extent qualify me to discuss this aspect of the legislation.

I am a lawyer by profession and my legal background includes experience in the Federal judicial system as a law clerk first to Judge Learned Hand of the Second Circuit Court of Appeals, and in the next year as law clerk to Mr. Justice Frankfurter. I practiced in Boston, Mass., with the firm of Robbs, Gray, Best, Coolidge, & Rugg, and thereafter for 2 years served as an assistant to Senator Leverett Saltonstall of Massachusetts.

The subject of chemical food additives has been of deep concern to our Department and to its predecessor, the Federal Security Agency, for a number of years. We are gratified that your subcommittee has taken and is taking the time to look into the various aspects of the problem thoroughly.

The Department, dealing as it does with the health, and education, and the welfare of the American people, is perhaps closer than any other to the everyday lives of all men and women in the country. And certainly the purity of the food that all of us eat and place before our children is of paramount importance. It is important not only that our food be safe but also that the housewife who buys and cooks it recognize that it is safe. She must have confidence in the farmer who grows it, in the processor and handler who make it available to her, and in the Government.

It was Abraham Lincoln who said that the Government should do for the people those things they cannot do for themselves. This comment was made at a time when the Government did not give much consideration to the purity of food.

It was not necessary in his day, for food then was generally grown and consumed in the same area. If the housewife did not grow the food her family ate, she generally knew, or knew of, the farmer who did.

The preparation of food was conducted principally in the home. Each housewife was in a position to determine for herself that the family dinner was what she wanted, that it had been properly handled and contained only those items accepted as safe.

All this has changed. The items on the table at an average meal today may have been grown thousands of miles away, and they may have been processed in several different factories, each far removed from the point of consumption.

New processes of great technological value require the addition of food of chemicals unheard of when ours was a predominantly agricultural economy.

It is plainly impossible for today's housewife to evaluate the suitability of her food as her grandmother did. So it becomes necessary for the Government to do a good part of the job for her.

The original Food and Drug Act of 1906 did not, nor does the present Food, Drug, and Cosmetic Act of 1938, require a manufacturer to establish the safety of a chemical before he adds it to food. Firms that are careless or irresponsible can add new substances to the food supply without any testing at all.

If they add materials of unknown or uncertain toxicity, we have no way to prevent it; and, if any of these substances are actually harmful, they cannot be eliminated from the food supply until someone, ordinarily the Government itself, develops the scientific evidence adequate to support legal action. Obtaining such evidence may require years. Meanwhile, the public health may be endangered.

In 1937 a drug manufacturer decided that sulfanilamide would be easier to take if it was in a liquid form rather than a tablet. He found a chemical, used primarily as an antifreeze, and made his elixir with it without determining whether the new drug would be toxic.

The drug killed over a hundred people before the Food and Drug Administration could get it off the market. This tragedy focused public attention on the need for proper testing of new drugs before they are marketed. As a result, the present law has a section that requires new drugs to be shown to be safe before they are sold.

This same requirement is essentially what is now proposed for chemical food additives. The danger of a disaster from untested drugs is as great today as in the thirties. The potential danger of food additives, indeed, is more insidious because it is a danger from the daily intake of small amounts of chemical substances which may affect the heart, the liver, the blood-forming systems, and so forth.

These are effects unlikely, in the absence of scientific animal testing which showed the toxic potential of the chemical, to be attributed to chemicals in foods.

I should emphasize here that the bulk of the food and chemical industries are to be commended for voluntarily adopting precautions to forestall detriment to the public health. The commendable actions of the great majority, however, cannot provide protection against the minority.

We have had some narrow escapes in the food field. We believe it is urgent that the Federal law be brought up to date to guard against disaster.

The unprecedented chemical research during and following World War II, together with the amazing advances in food technology that accompanied it, have pointed the way to thousands of possible new uses of chemicals in food.

The need for mandatory control has been recognized by the Congress for several years. Eight years ago, the House authorized the formation of a Select Commiteee To Investigate the Use of Chemicals in Foods. After extensive hearings, the committee submitted its report on June 30, 1952, Report No. 2356, 82d Congress. It stated in part:

> In conclusion, the evidence has convinced your committee that chemicals have been utilized in and on the food supply of the Nation without adequate and sufficient testing of their possible long-range injurious effect; that the public is entitled to greater protection with respect to the foods it must necessarily consume; and that such protection is not afforded by existing legislation, under which the Government may take no action until after the food has been placed upon the market and injury may have occurred.
>
> Your committee recommends, therefore, that the Federal Food, Drug, and Cosmetic Act be amended to require that chemicals employed in or on foods be subjected to substantially the same safety requirements as now exist for new drugs and meat products. Adequate provisions for a comprehensive judicial review of administrative decisions should be included in such an amendment.

The recommendations of the select committee have been accomplished in part by the enactment of the pesticide chemicals amendment in 1954, Public Law 518, 83d Congress.

This law provides the same type of control over pesticide chemicals as is now proposed for other food additives. It has in our opinion proved to be an excellent piece of legislation.

The Department did not submit a proposed bill to the last Congress. There were already a number of bills available for consideration, which presented various methods of dealing with new additives. We concluded last year that it would be well to draft in the Department a bill that represented our views.

The legislation we propose is before you as H. R. 6747. It would require a chemical additive to be tested properly before it is added to food. The evidence thus developed would be submitted to our Department and if it showed that the proposed use of the additive is safe, the Department would so indicate by a regulation stating the conditions under which the additive could be used. It would require a poisonous or deleterious additive to have functional value before safe amounts of it could be used in food.

There are several respects in which other bills before you differ from H. R. 6747. I do not propose to describe each of those differences because Commissioner George P. Larrick of the Food and Drug Administration, who follows me, will deal with them.

I would like to add, Mr. Chairman, that he also will have a prepared statement at such time as the committee is able to reach his testimony.

But I would like to discuss in some detail the procedural provisions of the bills now before you.

Before proceeding to a comparison of the merits of these provisions, I would like first to try to bring into clear focus the aim of the deter-

minations which would be provided for by each of the pending bills.

This aim, in the first place, is chiefly to regulate new additives, additives that have not heretofore been in use and whose safety has not been established.

Apart, therefore, from the initial period of transition during which additives now used without adequate evidence of safety would have to be properly tested, the required determinations would be prospective in effect.

A decision as to the safety of a new additive could not, in other words, deprive any manufacturer of an existing benefit. A determination that the safety of an additive had not adequately been established would at most prevent the realization of its potential economic value. It would not impose any economic loss.

A second aim is that such determinations should have the maximum possible future value in regulating the use of the substance in question. The proceeding should thus serve not simply the purpose of determining the safety of an additive as used by the manufacturer who initiated the proceeding, but of prescribing conditions for its use by all others in the same segment of the food industry.

A third aspect of the determinations to be made under this legislation, and this is true under each of the bills which you are considering, concerns the question whether or not the additive is safe under the conditions of its intended use.

The determination of this issue cannot rest merely on consideration of the inherent toxic properties of the substance in question. It requires, as you know from the testimony that has been presented by others, the consideration of at least two other questions:

(*a*) Whether or not there is any tendency of the substance, in combination with the other substances with which it would be used, to produce harm; and

(*b*) In cases where an excessive quantity could be harmful, what amount, taking into account the quantity likely to be consumed over a lifetime, is safe.

Any proceeding instituted under legislation in this field should obviously be capable of producing answers to these questions. It will frequently not be enough to say that the additive is "safe" or that it is "not safe."

It will be necessary in many cases to strike a balance, to conclude, for example, that an additive is safe under certain restrictions.

To sum up, any determination arrived at under legislation regulating the use of chemical additives will have, if the purpose of the legislation is to be served, the following three fundamental characteristics:

(*a*) Apart from the initial period of transition, it will be prospective in effect;

(*b*) It will govern future use of the additive by the industry at large; and

(*c*) It will on occasion strike a safe balance between conflicting evidence and competing considerations.

The determination will, in other words, be essentially legislative in character. It will have the function, not of adjudicating a claim, but of prescribing a rule for the future.

In applying these considerations to the legislation before you, it seems apparent that the task to be accomplished is unsuited to per-

formance, at least in its entirety, by a court. A court, in the first place, does not ordinarily occupy itself with making rules for the future.

A court does not have the power, moreover, to make rulings binding on persons other than the parties to the proceedings before it. Judicial procedures, finally, are not readily adaptable to the development of solutions reflecting intermediate adjustments between the positions of the parties.

Suppose, for example, that a manufacturer proposes to use X as an ingredient of Y. He has specified in detail the quantity that he proposes to use and the exact circumstances of its intended use. The Food and Drug Administration's scientists take the position that the quantities which the manufacturer proposes to use have not been shown to be safe, but they agree that the use of a smaller quantity under the described conditions would be safe.

Consistent with established judicial practice, the court would be required to rule either that the proposed additive under those conditions and in the quantity proposed is safe or that it is not safe.

It could not, without assuming functions foreign to the judicial process, say "We agree that the use of this additive in the proposed quantities has not been shown to be safe. We do not believe, on the other hand, that the protection of the public health requires that it be completely ruled out of food. We, therefore, rule that the use of a specified quantity under specified conditions, both more restrictive than proposed in the proceeding before us, would be safe."

If, on the other hand, the court's ruling is confined simply to the determination that the proposed use in the specified quantity would not be safe, the manufacturer must either acquiesce in the lower amount that the Food and Drug Administration would agree to approve, or else initiate a new proceeding under which all the available facts will be taken into account in establishing a rule specifying safe quantitative tolerances and conditions of use.

The disadvantages inherent in any attempt to confine a rulemaking function within the limitations of the judicial process are illustrated, we believe, by bills now before you that would, in effect, provide for a trial de novo of all the issues arising in a determination of the potential hazard to health of a chemical additive.

There are four such bills: H. R. 366, H. R. 8930, H. R. 8629, and H. R. 10404. H. R. 366 would have the data with regard to safety of an additive submitted to the Secretary, generally by a manufacturer, and would have the Secretary reach a decision based on the data.

But if the Secretary decided that the safety of the additive had not been established, the manufacturer could notify the Secretary that he intended to employ the additive anyway.

The Secretary would then have the opportunity of suing in a district court for a declaratory judgment as to "whether or not the additive has been adequately pretested and thereby shown safe for use under the conditions of its intended use."

This declaratory judgment procedure would thus leave uncertain in a case where the court ruled adversely to the manufacturer whether or not the additive could be ruled safe in a lesser quantity or under other conditions.

By the same token, in a case where the court ruled in the manufacturer's favor, it would leave uncertain whether or not the additive could safely be used in a quantity larger than, or under conditions different from, the proponent's specifications. The judgment, in any case, would not be binding on any other manufacturer.

The other three bills providing for a de novo trial are H. R. 8390 and H. R. 8629, and H. R. 10404. These would permit the proponent of an additive to notify the Secretary, in case of an adverse safety decision, that he proposed to employ the additive, and the Secretary would have the opportunity of suing in a district court for an injunction to restrain the use of the chemical.

Again, the only issue would be whether the use of the additive under the conditions proposed by the manufacturer was or was not safe. And again the result would be binding only upon the parties.

A further disadvantage inherent in the judicial procedure provided for in these bills would result from the lack of uniformity consequent upon proceedings scattered among all the Federal district courts of the United States, and heard by different individual judges with varying interests and varying competence in the adjudication of scientific issues.

This lack of uniformity would be particularly disadvantageous in the administration of a function which, as we have pointed out, should have as one of its main goals the development of rules applicable to the food industry as a whole.

In view of these limitations on judicial procedure, some other procedure, not subject to the same restrictions, is indicated. The answer, we submit, is the standard administrative procedure provided for in H. R. 6747.

Under this procedure the first step would be study of the evidence bearing on the safety of an additive by Department scientists selected for their scientific ability and objectivity.

On the basis of their recommendation, the Secretary or his delegate would promulgate a rule prescribing the specific conditions under which use of the additive had been determined to be safe. Unless and until modified in the light of future proceedings, this rule would govern later use of the additive by all manufacturers.

Neither the Secretary nor his delegate, of course, would necessarily be a scientist, but I can assure you that the portion of the rule that depended upon scientific data would reflect the best judgment of the scientists of the Department.

And I think it is proper to emphasize that the scientists of the Division of Pharmacology of the Department's Food and Drug Administration, who would pass on chemical additives, are recognized throughout the world as being eminently qualified to judge the adequacy of data bearing on safety, and where adequate data are present, the safety of additives.

The availability to the Secretary of an expert scientific staff, indeed, in itself constitutes an advantage of the administrative over the judicial process in complex matters of this kind. A court, by contrast, would not have access to comparable staff assistance.

In the event that it seemed desirable either to the manufacturer or to the Department to obtain the judgment of scientists independent of both, either could get the evidence reviewed by an advisory com-

mittee of qualified experts selected by the National Academy of Sciences.

After review, the advisory committee would make a report and recommendations to the Department, which would then reach a decision. If the rule thus arrived at were not satisfactory to the proponent, he would have the right to a public hearing, following which there would be another ruling.

And if this decision were deemed objectionable, any person adversely affected could appeal it to the United States court of appeals, which would be required to determine whether or not it was supported by substantial evidence in the record of the hearing considered as a whole.

As you know, this is the procedure followed in many other situations where highly complex questions such as those relating to the safety of chemical additives are to be decided. It is basically the procedure provided in the Food, Drug, and Cosmetic Act for determining whether a new drug is safe or whether a proposed tolerance for a pesticide chemical is safe. In the case of new drugs, there is no provision for an advisory committee, and, through oversight when the law was passed in 1938, the appeal is to the district rather than the circuit court.

One other major consideration reinforces our preference for the administrative procedure and judicial review provisions of H. R. 6747. This concerns the manner in which questions of doubt are resolved, the problem, in other words, of burden of proof.

It would be the responsibility of the Food and Drug Administration under any of the proposed bills to protect the public health. This would be the sole interest represented by it as one of the parties to any proceeding, whether administrative or judicial. The manufacturer, on the other side, would have no such direct responsibility and no such exclusive interest.

When the issue, therefore, is whether or not a given additive is safe under the conditions of its intended use, which way should any doubts be resolved? Should they be resolved in favor of the considerations that led the manufacturer to want to employ the additive, or should they be resolved in favor of a requirement that its use be restricted until such time as more persuasive evidence of its safety can be adduced?

We think that the answer to this question should be clear. Yet under any law that required the Food and Drug Administration to initiate proceedings to restrain the use of an additive or to have its use declared unsafe, the burden of proof would be upon it. Questions of doubt would therefore have to be resolved against it.

We are firmly convinced that the public interest is at stake, the protection of health, is of such magnitude as to forbid subjecting it to this kind of risk.

These, then, are the reasons why we advocate the provisions of H. R. 6747. The same considerations, I understand, were persuasive to this committee when it considered and rejected the judicial-trial approach in its study of bills that preceded the passage of legislation to control pesticide chemical residues on raw agricultural commodities, Public Law 518, 83d Congress, mentioned above. They are reflected also in the testimony presented on behalf of the Judicial Conference of the

United States by Chief Judge Biggs in connection with this legislation at the hearings held in the 84th Congress and again last year.

The considerations which I have mentioned bear also on the question, raised by others before your committee, as to what should be the function or duty of a court of appeals in reviewing, on the basis of the administrative hearing record, the Department's findings of fact which underlie the order under review.

H. R. 6747 incorporates by reference the relevant provision of the pesticide chemicals amendment to the act, which is that the—

findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole;

I repeat—

when considered on the record as a whole,"

not alone on that part of the record which happens to be in line with the finding.

There has been considerable misunderstanding evidenced on this point during the hearings, a misunderstanding based on the fact that the former so-called substantial evidence rule prevailing before the Administrative Procedure Act was often understood and applied much more narrowly and therefore gave rise to much dissatisfaction.

The broader review called for by the present bill is the rule of the Administrative Procedure Act that now applies to direct judicial review of any regulatory action under the Food and Drug Act had on the basis of an administrative hearing record, including orders involving new drugs.

One industry viewpoint, perhaps overlooking how broadly, as I shall show, the present rule has been applied, is to the effect that the court's function in reviewing administrative fact findings which underlie the Department's safety regulations for food additives should be broader than the rule which now applies to judicial review of other food and drug regulations.

It has been suggested, for example, that the reviewing court should be permitted to set aside the Secretary's findings unless—

supported by the weight of the evidence in the record as a whole.

This would seem to call upon a court to substitute its own judgment for that of the expert administrative agency on questions of the relative weight of conflicting evidence, including, as would be likely in these cases, the relative weight of fairly conflicting views and opinions of scientific witnesses, and then to sustain or strike down the findings of the Department depending on whether they are in accord with the weight of the evidence found on the court's own scales.

This, I believe, would be objectionable for largely the same reasons as a completely de novo proceeding. It is, moreover, not easy to see why food additives should be subject to a rule different from the one applied to other regulations under the Act.

In this connection, I should like to stress two things. In the first place, we are here dealing with judicial review of quasi-legislative rulemaking, not of administrative adjudication. The court is to pass on the validity, not the scientific evaluation as such, of the administrative rule, and the findings of fact are to be reviewed only in that connection. To go further would vest a nonjudicial function in the courts.

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In the second place, under the rule of review we propose, the court has remarkably broad latitude in reviewing the administrative fact findings. Under the settled construction of that rule, the courts, while not entitled to displace the agency's choice between two well supported but conflicting views of the evidence, and while giving respect to the agency's expertness in its specialized field, are not indifferent to considerations of the weight of the evidence to the extent that these properly bear on the question whether the administrative findings have substantial support in the record considered as a whole.

The rule was authoritatively expounded by the Supreme Court in *Universal Camera Corp.* v. *National Labor Relations Board* (340 U. S. 474, 1950), to which Chief Judge Biggs has referred you. The rule, said the Court, definitely does not authorize a method of review whereby a court determines the substantiality of evidence supporting an administratives decision

> merely on the basis of evidence which in and of itself justified it, without taking into account contradictory evidence or evidence from which conflicting inferences could be drawn. * * *
>
> The substantiality of the evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirements * * * that courts consider the whole record. Committee reports and the adoption in the Administrative Procedure Act of the minority views of the Attorney General's Committee demonstrate that to enjoin such a duty on the reviewing court was one of the important purposes of the movement which eventuated in that enactment * * *.
>
> Congress has * * * made it clear that a reviewing court is not barred from setting aside an agency's decision when it cannot conscientiously find that the evidence supporting that decision is substantial, when viewed in the light that the record in its entirety furnished, including the body of evidence opposed to the, agency's, view * * *.
>
> The agency's findings are entitled to respect; but they must nonetheless be set aside when the record before a court of appeals clearly precludes the agency's decision from being justified by a fair estimate of the worth of the testimony of witnesses or its informed judgment on matters within its special competence or both (Id., at pp. 487, 488, 490).

And on the same day, in *National Labor Relations Board* v. *Pittsburgh Steamship Co.*, 340 U. S. 498, at page 592, also mentioned by Chief Judge Biggs, the Supreme Court said in affirming a lower court's application of the same rule of review:

> The court of appeals painstakingly reviewed the record and unanimously concluded that the inferences on which the Board's findings were based were so overborne by evidence calling for contrary inferences that the findings of the Board could not, on the consideration of the whole record, be deemed to be supported by "substantial" evidence.

Surely, then, this is broad enough to constitute a very high standard of fairness in the review of administrative rule making, especially where, as here, complex technical and scientific judgments are likely to be at the heart of the so-called questions of fact. Moreover, as the Court said in the Universal Camera case:

> Since the precise way in which courts interfere with agency findings cannot be imprisoned within any form of words, new formulas attempting to rephrase the old are not likely to be more helpful than the old.
>
> Thereafter no talismanic words that can avoid the process of judgment. The difficulty is that we cannot escape, in relation to this problem, the use of undefined defining terms.

I thank you for this opportunity of acquainting you with the Department's position with respect to a portion of the bill and corresponding portions of other bills before you.

Mr. WILLIAMS. Thank you very much, Mr. Richardson. Does that conclude your statement?

Mr. RICHARDSON. Yes, it does, Mr. Chairman.

Mr. DINGELL. Thank you, Mr. Chairman. Mr. Richardson, I assume that the statement which you have set forth this morning reflects no change which we had heard in the position of various witnesses who appeared on behalf of the Department at the last time hearings on this subject were held, is that correct?

Mr. RICHARDSON. That is correct to the best of my understanding.

Mr. DINGELL. In other words, H. R. 6747 still represents the Department's favorite piece of legislation, is that correct?

Mr. RICHARDSON. Yes, it does. We have not actually appeared before in support of this particular bill. This is our first appearance in this Congress.

Mr. DINGELL. Let me ask you just a couple of brief questions here. You discussed on page 6 of your statement the problem of new additives. I notice there was no mention of the existing additives in your statement. The point I make is this: I assume that H. R. 6747, if adopted, will enable the Department to compel persons present using additives to come forward and to establish safety for those same additives that are presently being used in the same way they would have to establish safety for new additives; is that correct?

Mr. RICHARDSON. It is except with respect to additives now in use that are generally recognized by competent experts as safe. Those additives would be outside of the scope of chemical additives as defined by the bill, and therefore not subject to the same proceures as would new additives, or existing not generally recognized as safe.

Mr. DINGELL. In other words, we are giving a grandfather clause to a certain very large class of present additives, is that right?

Mr. RICHARDSON. Yes.

Mr. DINGELL. I am very concerned about that. I am very concerned about the safety to that kind of practice. I would like to hear an expression of views from you on that particular subject.

Mr. RICHARDSON. I could go into it further, Mr. Dingell, but I think it might be desirable to leave that subject for elucidation by Mr. Larrick, who does propose to go into it at some length. I might say briefly that with respect to existing additives generally speaking, a large group, such as table salt, would be classified as generally recognized as safe by competent experts. These would be additives as to which there was no substantial question of safety, which have been used over a long period. These, as I have said, would be outside of the definition of chemical additives. Any others with respect to which there was doubt as to safety would be subjected to a transitional period of initially 18 months, subject to extension by another year, during which they would have to come forward with evidence of safety, just as would a new additive.

Mr. DINGELL. You say other additives presently being used, exclusive of a class like common table salt.

Mr. RICHARDSON. Yes.

Mr. DINGELL. I think I will pursue this with Commissioner Larrick of whom I might say I have the greatest respect. Thank you very much, Mr. Chairman.

Mr. WILLIAMS. Mr. Bush.

Mr. BUSH. Mr. Richardson, you spoke of new additives that are being considered or being used. Are they additives that replaced some of the older additives that are being used today?

Mr. RICHARDSON. I suppose some of them would be, Mr. Bush. In some cases they would be additives developed for uses that we have not now thought of at all.

Mr. BUSH. Have these new additives that you speak of been tested and approved by the Department of Health?

Mr. RICHARDSON. They would be required to be tested. That is the main purpose of the legislation. They have not been tested. Of course, I was referring in that context to new additives that have not yet come on the market at all or have not yet been developed. With respect to any additives that are already in use the provisions that Mr. Dingell inquired about would apply.

Mr. BUSH. That is one of the major reasons that you feel there must be some legislation enacted to take care of the situation?

Mr. RICHARDSON. That is correct, sir.

Mr. BUSH. That is all, Mr. Chairman.

Mr. WILLIAMS. Mr. Loser.

Mr. LOSER. Thank you, Mr. Chairman.

Mr. Richardson, under the review provisions of H. R. 6747 would you say that they are different from the review provided in Federal statutes with references to other administrative agencies?

Mr. RICHARDSON. Generally they are the same, because what we do here in effect is to incorporate the relevant provision of the Administrative Procedure Act. The language in question here is incorporated by reference to the pesticide chemical amendment itself, but the language that applies is the same.

Mr. LOSER. You say that the method of review of any administrative order of the Department, as set forth in H. R. 6747 is substantially the same as in the Administrative Procedure Act.

Mr. RICHARDSON. I believe it is exactly the same.

Mr. LOSER. And the position that you are now taking here is the position advocated by Judge Biggs when he appeared before this committee last year?

Mr. RICHARDSON. Yes, it is.

Mr. LOSER. Then H. R. 6747 differs from these other bills that you have referred to in that the manufacture, before any food additive may be used by him, must first be shown to be safe and the result of his findings submitted to the Commissioner before it may be used?

Mr. RICHARDSON. That is correct.

Mr. LOSER. That is the major difference between H. R. 6747 and the other bills that are pending before this committee.

Mr. RICHARDSON. Yes, with slight qualification. They would also require evidence of safety to be submitted initially to the Commissioner. The difference between H. R. 6747 and the other bills referred to in my prepared statement arises with respect essentially to the next step, because under those bills if the proponent of the additive—the petitioner—disagreed with the proposed regulation by the Commissioner, he could go ahead and market the additive anyway unless the Commissioner proceeded by way of injunction or declaratory judgment. The result in either case would be to throw the proceeding into a court for determinations of fact.

Mr. LOSER. The pending bills before this committee other than H. R. 6747 put the burden of proof on the Commissioner by proceedings in court that it is unsafe.

Mr. RICHARDSON. Yes, we would so construe the other bills mentioned in my prepared statement.

Mr. LOSER. That is all.

Mr. DINGELL (presiding). Dr. Neal?

Mr. NEAL. Mr. Richardson, it is pretty well recognized by your agency that most of the additives that are now being used by food processors have been proven safe, is that true? In other words, there is not any question in your mind that the majority of the additives that are being used today are safe. Is that true?

Mr. RICHARDSON. I would think that certainly was true, Dr. Neal. Where the line would fall between those generally recognized as safe and therefore outside the scope of the act, and those in use which would no doubt have to be shown to be safe under the act, is the question that I think Mr. Larrick could deal with much better. But I am sure that it is true that the vast majority of all additives now in use would ultimately be found to be safe, either at the very outset, because they were so recognized generally by competent experts, or in the next stage as the result of proceedings under the act.

Mr. NEAL. From your observation and your experience would you say that food processors are considering any great number of new additives at this particular time? Are the chemical discoveries bringing forth any knowledge which might lead you to believe that the processors of food are apt to be initiating a move to put additional additives into food?

Mr. RICHARDSON. The technology of this field is in very rapid development, and there are undoubtedly a very great many additives now being developed and tested by manufacturers which, if found useful, will undoubtedly be offered to the market. The number of those being used has grown very rapidly over the past generation and will undoubtedly continue to grow.

I ought to add in this connection, Dr. Neal, that one of the important issues that would be considered under this legislation is not the safety in an absolute sense of any additive, but rather the quantities and conditions of its use. It would be safe taking into account the quantity of it that would be consumed over a lifetime, its use in other foods, and so on. So there well may be necessary regulations as to the manner and quantity of use of a certain additive if it were perfectly clear that its use in those limited quantities and for those specified purposes would be safe.

Mr. NEAL. I believe I have one other question. From your experience, do you think any of the additives that have been used in processing of foods up to date are at this time by reason of experience of use indicating any tendency whatsoever to develop conditions that are unfavorable to the health of human beings?

Mr. RICHARDSON. I would say, Dr. Neal, that I cannot answer that question directly and would like to ask Mr. Larrick to pursue it further. I would like to say this: As we see the problem, in the first instance it is one of our simply not knowing what may be the deleterious effects of the usage of an additive, because we have not heretofore had the power to require the submission of evidence of its safety.

So that it would only be in the case where some manifestation of obvious harm occurred, as in the case of the sulfanilamide example that I used, that we would be definitely able to say that an additive would be proscribed.

Mr. DINGELL. You mean under the existing law?

Mr. RICHARDSON. Yes. Beyond that I believe perhaps Mr. Larrick could answer.

Mr. LARRICK. Do you want me to answer at this time or after I testify?

Mr. RHODES (presiding). Are there any further questions?

Mr. NEAL. That is all I have.

Mr. LOSER. Since Mr. O'Hara is the author of one of these bills, I would be happy to have him interrogate Mr. Richardson or any suggestions that he has to offer.

Mr. O'HARA. Thank you, sir.

Mr. WILLIAMS. Mr. O'Hara.

Mr. O'HARA. Mr. Richardson, have you practiced in your general practice before any of the regulatory agencies?

Mr. RICHARDSON. Yes, I have, Mr. O'Hara.

Mr. O'HARA. Specifically what agencies?

Mr. RICHARDSON. The Securities and Exchange Commission, and the Interstate Commerce Commission.

Mr. O'HARA. Generally speaking, is there not a good deal of criticism of the Administrative Procedures Act by those who practice under it?

Mr. RICHARDSON. I believe there is among some of those. I have no definite impression of how general that criticism is.

Mr. O'HARA. I think Judge Biggs even indicated that there was a good deal of criticism of it and need for reform. I believe the American Bar Association has been working upon that problem, has it not, in the matter of suggested legislation and changes in the Administrative Procedures Act?

Mr. RICHARDSON. I believe that is so.

Mr. O'HARA. Is not one of the criticisms of the act the difficulty of getting a review either by injunctive relief or by trial de novo? Is that not one of the problems which the practitioners have in this matter of the Administrative Procedures Act?

Mr. RICHARDSON. I believe that many practitioners do have that feeling. I think it may be relevant at this point to emphasize the thought expressed in connection with the question of burden of proof in my testimony to the effect that we are dealing in this situation wih a responsibility for the protection of the public health as distinguished from the interest of a particular manufacturer in the use of a particular food additive. I think that practitioners' views on this score are very often influenced by the feeling that the proceeding resulting in ultimate determination ought, from the beginning, to be an ordinary adversary proceeding in the courts. But I am not sure with the public interest in view that is really an appropriate way of looking at what we want to accomplish. The Food and Drug Administration, like other regulatory agencies similarly placed, does have a responsibility to the public interest, and the ultimate question really is how doubts as to whether or not the public interest is served should be resolved. I think it is understandable that a practitioner should

want to feel that he was appearing on the same footing in a court as he does against another private litigant. But I am not sure that he is right in so feeling.

Mr. O'HARA. I think it has grown up to be the viewpoint of the regulatory agencies that they should be supreme to the Supreme Court, isn't that the situation?

Mr. RICHARDSON. I certainly don't think that would be an accurate characterization of our feeling.

Mr. O'HARA. There seems to be that feeling that they should have first, last, and final word on any question of what is good for the public. Do you not think that the courts have the same responsibility to the public that any regulatory agency has, Mr. Richardson?

Mr. RICHARDSON. Of course they do have a very broad and fundamental responsibility to the public, but we are really dealing with a somewhat narrower question, which is the question of how doubts on issues of scientific fact are resolved, and the court is apt to be governed and necessarily governed in its determinations of fact by the relevant rules applicable to burden of proof.

Mr. O'HARA. Under my bill, H. R. 366, the burden of proof is on the petitioner both I think before your agency and before the court as to the safety. Isn't that a wise provision for the safety of the chemical additive?

Mr. RICHARDSON. I think it is a difficult question of where the initial burden is discharged and where ultimately issues of fact are resolved. There is the question of what is sufficient for the petitioner to sustain the burden of proof. If he simply comes forward with evidence of safety, is this enough? What we are saying essentially is that there ought to be a determination taking into account all the data made by competent experts whose responsibility is to the public and providing for an opportunity for both sides to call upon independent experts named by the National Academy of Sciences.

Mr. O'HARA. What responsibility does that so-called advisory committee have? Do they take an oath of office of any kind? Are they subjected to cross-examination or to their qualifications by the petitioner? Does the petitioner have any opportunity to examine them as to possible bias?

Mr. RICHARDSON. If a proceeding came to the hearing stage, the conclusions or findings of an advisory committee would, if relevant and material, be made a part of the record before the hearing examiner, but at that point that data would be subject to cross-examination or testing by the questioning of counsel on the other side, just as would any other evidence submitted to the hearing examiner.

Mr. O'HARA. I am speaking of your advisory committee now, this super committee that is brought in.

Mr. RICHARDSON. This is an advisory committee, advisory to the Secretary in the course of his administrative determination.

Mr. O'HARA. Who sets up that committee.

Mr. RICHARDSON. The National Academy of Sciences.

Mr. O'HARA. But who appoints them to act? The Secretary does, doesn't he?

Mr. RICHARDSON. He would not name the individuals. Either he or the petitioner could elect to call upon the judgment of the advisory committee.

Mr. O'HARA. How would you know what type of qualifications they had? Who passes on that?

Mr. RICHARDSON. I think either side would.

Mr. O'HARA. Where is there any provision in H. R. 6747 for any such examination?

Mr. RICHARDSON. What I am trying to make clear, Mr. O'Hara, is that one, I think, needs to see this first on the basis of a proceeding taking its ordinary course in which no objection is made to the proposed regulation by the Food and Drug Administration. In that case whatever advice the advisory committee gave would be taken into account with any other data before the Secretary. But if the petitioner objected to the proposed regulation he could then ask for a hearing.

At the hearing the Department would need to submit to the hearing examiner all its evidence, including any evidence that it proposed to rely upon that had been brought to its attention by the advisory committee. At that point the advisory commitee's recommendations would be subject to cross examination like any other evidence presented to the hearing examiner.

Mr. O'HARA. Why is there the feeling of those who practice before your agency and other regulatory agencies? Isn't there a feeling that they are pretty much circumscribed? The hearing examiner holds the hearing. The Department brings in the witnesses. The petitioner, of course, brings in his witnesses. Here are a group of scientists on behalf of the petitioner who are in disagreement with the scientists who represent the Food and Drug Administration. Who resolves that difference? Ultimately the Commissioner, does he not, and he is not going to go against his own people. Isn't that the situation?

Mr. RICHARDSON. I think it is important to have in mind, Mr. O'Hara——

Mr. O'HARA. I would like to have the answer to that question.

Mr. RICHARDSON. I could only answer it by saying that I do not think it can be assumed that the Commissioner, assuming that he is serving as the Secretary's delegate for this purpose, would automatically favor his own people.

Mr. O'HARA. Has he ever been known not to?

Mr. RICHARDSON. He has been known many times to overrule or to modify the conclusions of his own people. I think it is significant in this connection that we administer substantially identical provisions applicable to pesticides, and almost similar provisions applicable to new drugs on the whole with a very high level of goodwill and cooperation between the manufacturers and the Food and Drug Administration.

Mr. O'HARA. I think dealing with pesticides may be one question and it would be quite a different question in dealing with drugs and dealing with chemical additives in foods. Don't you agree with that?

Mr. RICHARDSON. I think it is significant in the case of new-drug provisions which are in substance the same—they are the same so far as the applicant for a ruling with respect to a new drug submits scientific data with respect to its safety just as would the manufacturer of a food additive—and in the years since that law has been in effect, there has been only one case of a contested hearing before the Commissioner or the Department.

Mr. O'HARA. If you have a violation of the drug law you go into Federal district court, do you not?

Mr. RICHARDSON. In the case of new-drug applications we would go into a district court for review of the record as a whole in the same manner in which this legislation provides for review by a court of appeals. We would not go into the court for a trial.

Mr. O'HARA. There is quite a difference in the two proceedings. Where you proceed in district court you are in trial, are you not?

Mr. RICHARDSON. Not under the new-drug law.

Mr. O'HARA. I am not speaking of the new drug law. I am speaking of your general provision which applies to your going into district court.

Mr. RICHARDSON. With respect to seizure and condemnation of substances determined to be deleterious or toxic, it is true we proceed against some product which the Food and Drug Administration believes to be harmful. What I am trying to make clear is that under the provisions of law which like this one call for preclearance of the substance through submission of test data in advance to the Food and Drug Administration, in those latter situations the court review called for is the same in scope as would be the court review called for under this proposed legislation.

Mr. O'HARA. Let us go back to the situation where you proceed by libel against the drug manufacturer. It is tried in district court, is it not? How many of such actions have you had of that nature?

Mr. RICHARDSON. I would like to ask Mr. Larrick.

Mr. LARRICK. Many thousands, Mr. O'Hara.

Mr. O'HARA. How many of them have ever been appealed to the circuit court from the trial by the district court?

Mr. LARRICK. A great many.

Mr. O'HARA. Have they gone up?

Mr. LARRICK. To the Supreme Court? Yes, sir, many times.

Mr. O'HARA. It was my understanding when we had the hearing last summer that there was some testimony where there had been only one appeal from that provision.

Mr. LARRICK. That is on new drugs, Mr. O'Hara. That is on the new drug proceeding.

Mr. O'HARA. I was misled on that. But it has not been such a burden on the Department to have to try the drug cases in the Federal district court, has it?

Mr. RICHARDSON. Because the new drug provisions are substantially the same as those we are arguing for here.

Mr. O'HARA. You still go before the district court on them, do you not?

Mr. RICHARDSON. Yes, but as I have tried to indicate, the function of the district court in reviewing the record to determine whether or not the proposed regulation of the Department is supported by substantial evidence in the record as a whole is the same as the function of the court of appeals.

Mr. O'HARA. It still passes on the scientific questions and the questions of fact.

Mr. RICHARDSON. In the same manner and only to the extent that the court of appeals would do so under this proposed legislation. As I indicated in my testimony, the provision of the new drug act calling

for review by the district court was an inadvertent provision of the act.

Mr. O'HARA. What do you mean inadvertent? Both the House and the Senate passed it, did they not?

Mr. RICHARDSON. Mr. Harvey, could you expand on that?

Mr. HARVEY. The features in all other sections of the bill were changed to the circuit court. I was advised it was overlooked in the new drug provision.

Mr. O'HARA. It is amazing.

Mr. HARVEY. It is.

Mr. O'HARA. Mr. Richardson, why does your Department take the position, which is a growing complaint, of a feeling of these people that they do not have their day in court? Don't you think that fundamentally is an American tradition of people desiring to have a different opinion from the opinion of your Department to have a review other than the circuit court of appeals review, which is merely on the record, which in many instances is certainly highly unsatisfactory to those who have practiced a great many years. Why are you so opposed to giving these people, either by injunction relief or by trial de novo, a hearing before the district court?

Mr. RICHARDSON. I would like to restate the essential elements of the situation which led us to believe that the form of procedure called for by H. R. 6747 is a preferable one to the alternative of judicial trial.

Mr. O'HARA. It is preferable to you and your Department; is that the situation?

Mr. RICHARDSON. We think, for the reasons I have outlined, it is preferable for purposes of carrying out the purpose of this legislation. In the first place, we are talking here about developing a regulation which determines the amounts of a chemical additive that can be used in food, the conditions of its use, the kinds of foods that it can be used in, and that will be applicable to the use of this additive by all manufacturers, not just the chemical manufacturer who produces it, but the food processor, the baker, or whoever he may be, that puts it into food. This is essentially, as we see it, a rulemaking function as opposed to a judicial function deciding between the claims of two parties standing on equal footing with respect to some contested issue. As we see it, the Food and Drug Administration in regulating prospectively for the future the use of a new food additive has the responsibility of protecting an interest far broader than any interest represented by the applicant. We think, therefore—and since further the effect of the responsibility is as I have described it—that these considerations are better served by the kind of procedure we have proposed than they would be by a trial court's regular de novo proceeding.

Mr. O'HARA. Let me take that statement a little bit apart. Here is a new chemical additive. The petitioner comes in and states he believes it to be a safe chemical additive. It is tried before your department, is it not, by the scientists of your department who are the controlling witnesses on that side, and the scientists on the part of the petitioner? The trial examiner makes a finding or the Commissioner makes a finding one way or the other, based upon that evidence that these witnesses have given, is that not correct?

Mr. RICHARDSON. It is not just a finding one way or another. It may be a finding, taking into account all evidence and fixing condi-

tions of use of the chemical that are more restrictive than proposed by the manufacturer, but less so than some of the scientists whose views have been presented would have argued for.

Mr. O'HARA. If it goes to a trial court, what would the trial court be doing? He would be listening to the scientists on both sides, would he not? He would be listening to those on the part of the Department and those on the part of the petitioner and making his decision on the same grounds and to the same extent that your Department makes, is that not a fact?

Mr. RICHARDSON. With two essential differences. One, it is hard to see how a court could spell out conditions of use different than were argued by either side.

Mr. O'HARA. He would certainly have the advantage of having your scientists stating what they believe. He would have that testimony, would he not?

Mr. RICHARDSON. Yes, he would.

Mr. O'HARA. As to the exent of its use. So he would have before him a question of fact on which he could make findings that would be binding upon the petitioner. Is that not true?

Mr. RICHARDSON. Would not the issue be simply in essence whether the additive was safe or not safe?

Mr. O'HARA. Not necessarily. I don't think so at all. Do you take the position that the evidence would not be the same before the trial court as the record of hearing before your Department would be?

Mr. RICHARDSON. We would certainly concede that the evidence might well be and normally would be the same. The difference is with respect to the character of the determination made. We would say, and I have argued, that the procedure provided for should be adaptable to the spelling out of a regulation specifying the conditions under which——

Mr. O'HARA. Your regulation, of course, Mr. Richardson, could not be based upon anything but the testimony which is before you in the hearing, is that not true, in your Department?

Mr. RICHARDSON. It is.

Mr. O'HARA. That is identical with what the trial court would be up against.

Mr. RICHARDSON. With the differences that I have stressed. It is hard to see how a trial court would be in a position itself of framing a regulation designed to govern all manufacturers or users of the product. That is an odd sort of decree or result for a court to arrive at. I can see a court saying that I don't think the Food and Drug Administration has shown that this additive is unsafe, or the court saying, I would conclude on all the evidence before me that the additive is not safe. But that is of a very little help to the public at large or to other manufacturers, and it may not be of help even to the manufacturer where he concludes that it is not safe because it might be that a smaller quantity of the product or some limitations on the conditions of its use might properly be found safe.

Mr. O'HARA. Mr. Chairman, I think I have used up my time. Thank you.

Mr. RHODES. Mr. Loser.

Mr. LOSER. It is apparent that when this committee considers these bills in executive session that there will be a substantial controversy

about the method in which a judicial review maybe had on the findings of the regulatory agency. I would like to ask just a few questions, Mr. Richardson, about some provisions for court review under the Federal rules of procedure.

I believe under rule 52 (a) we find this language:

Findings of fact shall not be set aside unless clearly erroneous and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses.

Are you familiar with that provision?

Mr. RICHARDSON. Yes, in general, Mr. Loser.

Mr. LOSER. Is there a substantial difference between this provision and the provision that we find in H. R. 6747?

Mr. RICHARDSON. I don't think there is a substantial difference.

Mr. LOSER. That rule was considered in *U. S.* v. *the Gypsum Company*, 333 United States. I believe you find this statement in that ruling:

A finding is clearly erroneous when although there is evidence to support it the reviewing court on the entire evidence is left with the definite and final conviction that a mistake has been committed.

That is a review and a finding of the court under the Federal rules of procedure, rule 52. Isn't that substantially the method of review as set out in H. R. 6747?

Mr. RICHARDSON. Yes, it is.

Mr. LOSER. Although the language employed is somewhat different.

Mr. RICHARDSON. That is correct.

Mr. LOSER. In the Emergency Rent Control Act, section 204 of the public law of the 81st Congress, I believe, we find this:

Evidence in the record is not of sufficient weight to justify such decision.

Mr. RICHARDSON. There would be a difference between language referring to findings supported by the weight of the evidence and the language we propose, "if supported by substantial evidence when considered in the record as a whole."

Mr. LOSER. Then in section 632 of title VI of the Public Health Service, the Hill-Burton Act, we find findings of fact, and so on, unless substantially contrary to the weight of the evidence, meaning unless the findings of fact are contrary to the weight of the evidence, they shall become final. Is that the substantial evidence rule on review?

Mr. RICHARDSON. I believe substantially so.

Mr. LOSER. In Taft-Hartley, we find, "Findings with respect to questions of fact, if supported by substantial evidence in the record, considered as a whole." That is the substantial evidence rule, isn't it, that we find in the Administrative Procedure Act?

Mr. RICHARDSON. Yes.

Mr. LOSER. Is that the same in H. R. 6747?

Mr. RICHARDSON. Yes, it is.

Mr. LOSER. Subversive Activities Control Act:

Findings of the Board as to fact, if supported by the preponderance of the evidence, shall be conclusive.

That is just a little bit different from the substantial evidence rule, isn't it?

Mr. RICHARDSON. Yes, that sounds like a slightly less strict standard.

Mr. LOSER. Tell me this, Mr. Richardson, if you know. Is there any provision in any of the Federal statutes with reference to a review of a regulatory agency where the review is by trial de novo?

Mr. RICHARDSON. None that I know of, Mr. Loser.

Mr. LOSER. If the review under the substantial evidence rule is in the district court or the court of appeals, what is the difference?

Mr. RICHARDSON. It makes no difference.

Mr. LOSER. It makes no difference whatsoever whether it is in the district court or the court of appeals if it is under the Administrative Procedure Act.

Mr. RICHARDSON. That is entirely correct.

Mr. LOSER. You say you don't know of any review by trial de novo?

Mr. RICHARDSON. No. Of course, it is fair to say where you have review by trial de novo it is really not review at all. It is a new proceeding which thereupon disregards whatever may have occurred before that trial by way of an administrative proceeding.

Mr. LOSER. Of course, if a trial de novo is had that means that the witnesses will appear before a court and jury as they originally appeared before the examiner, is that right?

Mr. RICHARDSON. That would be my understanding.

Mr. LOSER. It would be a trial by jury in the de novo hearing.

Mr. RICHARDSON. I suppose it could be, depending upon what the statute provided. It could be a trial before a judge alone.

Mr. LOSER. If a question of fact is presented and all of them are questions of fact that means trial by jury if it is a hearing de novo, is it not?

Mr. RICHARDSON. I think if it were assimilated to equity proceedings you could have a trial before a judge where there were no criminal penalties attached.

Mr. LOSER. In any proceedings where the question of fact arises, if either of the parties wants to submit a disputed question of fact to a jury, that can be done as a matter of right, can't it?

Mr. RICHARDSON. I am frank to say, Mr. Loser, I did not know it was a matter of right. I would agree in any case that the character of the findings——

Mr. LOSER. I don't mean to insist that the chancellor, as they call them in my State, or the judge ruling on a question of equity, is bound by the findings of the jury, but he can submit to the jury questions to be answered by the jury on disputed questions.

Mr. RICHARDSON. Yes. I am aware that some equity courts do call upon a jury for that purpose.

Mr. LOSER. But you say you are not aware that is a matter of right.

Mr. RICHARDSON. In the Federal courts, I did not think so. In any case, I would agree that the point you make is a valid one, in either case. The issues of fact to be found would be, whether found by a judge or by a jury, found in the same way after listening to all the evidence and determining credibility and considering the applicable burden of proof and so on.

Mr. LOSER. And any method of review in this situation must be ultimately predicated upon the testimony of some scientists, whether they be in your Department or representing the manufacturers?

Mr. RICHARDSON. Yes.

Mr. LOSER. I believe that is all.

Mr. DINGELL. Mr. Chairman, could I be recognized?

Mr. RHODES. Mr. Dingell.

Mr. DINGELL. Mr. Secretary, I have been extremely interested in the line of questions by my distinguished friend from Minnesota, Mr. O'Hara, and my very good friend, Mr. Loser. First of all, let me see if I can nail down the position of the Department.

Would it be fair to say that the dangers inherent in food additives are of the highest order to the people of this country? In other words, in an additive that is dangerous to the food, the danger to the people is of the very highest order, because they are in the more or less helpless position of being a captured consumer, because they don't have any choice of what goes into the food.

Mr. RICHARDSON. That is certainly true with respect to the potential dangers.

Mr. DINGELL. I am not indulging in scare tactics. I am merely stating what might be considered as logical and ultimate. To go further tl an that, would I be fair in stating that it is the position of the Department that, because of this very tremendous danger which is inherently present in the distribution of food which is subject to food additives, we should place every procedural safeguard on the side of the public interest, on the side of the people, and not on the side of those who have, after all, an economic interest in the distribution of this food and the use of food adidtives in which they have spent a substantial amount of money to develop and place on the market. It that a fair statement?

Mr. RICHARDSON. Yes; certainly, it is, consistent with assurance of fairness to the applicant and the manufacturer. We would agree with that statement.

Mr. DINGELL. I assume, in views of the Department, there are adequate safeguards present in the legislation which you offer to assure fair play in the traditional concept, as my good friend Mr. Loser has developed, under the existing Administrative Procedure Act. Am I correct in that, sir?

Mr. RICHARDSON. You are.

Mr. DINGELL. Let me go just one little bit further. I would like to go now into the business of the trial de novo. Would it be a fair statement to say that, very frequently, under existing law and under existing review, a court review of a finding of the Food and Drug Administration can drag on for months, if not years? Wouldn't that be a fair statement?

Mr. RICHARDSON. I believe that is sometimes true.

Mr. DINGELL. And they have, in fact, done so. Is that not also a fact?

Mr. RICHARDSON. Yes.

Mr. DINGELL. On a great number of instances. This dragging on for months and years which takes place can take place not only in 1 district, but, in instances, of 2 or 3 or even 4 district courts in various parts of the country; is that not also correct?

Mr. RICHARDSON. Yes.

Mr. DINGELL. In addition to that, under existing practice it is also possible for this judicial review to begin and halt and to be concluded and to be started in different phases, and on different questions involv-

ing the same product in a number of different courts, primary and appellate, in different parts of the country at the same time. Is that not also a correct statement?

Mr. RICHARDSON. That is true. With respect to additives, it would be possible for different manufacturers to initiate different proceedings, the results of which would not be determinative on the others.

Mr. DINGELL. Would it be a fair statement to say that under H. R. 366 we could find this same complex situation of conflicting results and competitive suits perpetuated in the case of food additives in courts in different parts of this country? Would that not also be a fair statement?

Mr. RICHARDSON. I think that would be possible.

Mr. DINGELL. Would you say that is in the best interests of the people?

Mr. RICHARDSON. We don't think that it would be; no. We think the result which you described, in effect, nullifies the responsibility of the Food and Drug Administration, in the light of all the competent scientific evidence, to determine conditions under which an additive can safely be used and transfer the whole proceeding into a court, leaving no regulation applicable in the meanwhile.

Mr. DINGELL. Thank you.

Mr. O'HARA. Mr. Chairman, I would like to ask a couple of questions. It is true, under your own procedure, an appeal could be taken to the circuit court of appeals and then to the Supreme Court and would also consume several years. Is that not true?

Mr. RICHARDSON. Yes.

Mr. O'HARA. So, it does not apply just to H. R. 366?

Hr. RICHARDSON. Except to the extent that a trial de novo, in effect, involves a considerably longer process with all the steps available and normal to a factfinding contested proceeding.

Mr. O'HARA. Under H. R. 366, you have a right to come in and enjoin, do you not, the sale of that product with the chemical additive or the food in which it was used? You have the same right, do you not, under H. R. 366 that you would have under any other legislation?

Mr. RICHARDSON. I believe we would have the right to seek such an injunction. Would it not be discretionary with the court whether to grant it? I believe, further, the burden of proof in seeking the injunction would be upon us.

Mr. O'HARA. You don't recommend that all appeals be abolished on these matters, do you?

Mr. RICHARDSON. No; I do not.

Mr. O'HARA. I was curious about that, Thank you.

Mr. RHODES. Are there any further questions of Mr. Richardson? If not, thank you, Mr. Secretary.

Mr. RICHARDSON. Thank you, Mr. Chairman.

Mr. RHODES. Our next witness will be the Honorable George P. Larrick, Commissioner of the Food and Drug Administration of the Department of Health, Education, and Welfare.

STATEMENT OF HON. GEORGE P. LARRICK, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. LARRICK. Thank you.

Mr. RHODES. Before you proceed, Mr. Larrick, I have a few items for the record. If there is no objection, a statement from the Flavoring Extract Manufacturers Association and a statement by Mr. Frederick S. Leinback will be included in the record.

(The statements referred to follow:)

FLAVORING EXTRACT MANUFACTURERS' ASSOCIATION OF THE UNITED STATES FOOD ADDITIVE COMMITTEE RECOMMENDATIONS TO THE HOUSE HEALTH AND SCIENCE SUBCOMMITTEE OF THE INTERSTATE AND FOREIGN COMMERCE COMMITTEE

The Flavoring Extract Manufacturers' Association of the United States is a long-established trade association representing the principal factors of the flavoring extract industry.

The proposed legislation on food additives directly affects its membership. There are many unusual and some unique features which should be considered by this committee in order to arrive at the most effective and practical legislation. Among these factors are the following:

(*a*) Flavoring substances occur naturally in all food products, and many of the substances now added, or proposed to be added in a given food product, are obtained originally from, or occur naturally in, other foods.

(*b*) Most flavoring substances occur or are added in very small amounts compared with other food components.

(*c*) Flavors, including most added flavors, are similar in chemical and physical properties to other food components.

(*d*) Most flavoring materials are significantly volatile.

(*e*) Few flavoring compounds are consumed as such, but almost all are components, often quantitatively minor components, of other food items.

(*f*) For the foregoing reasons, the isolation, identification, and determination of flavor components at the levels at which they are actually used in foods is a difficult and frequently impossible task.

(*g*) Although the use of flavors is essential to impart palatability to food, they are frequently used at such low levels that the total annual volume and value of the flavor are quite small. Many of the companies which produce flavors are small businesses. These companies could not afford nor could the annual volume of these products justify, excessively elaborate testing programs.

(*h*) Although flavors contribute an indispensable palatability to foods, the total commercial volume of many important individual flavoring substances is extremely small because they are effective at low levels of use in foods. Administrative procedures, therefore, should, if possible, be so designed as not to confer an impossible burden upon these producers of economically small, but important, food ingredients.

(*i*) Many flavor compounds are inherently self-limiting in use, since excessive amounts render the food in which they are used unpalatable.

The Flavoring Extract Manufacturers' Association of the United States supports the general principle of pretesting of new food additives to insure their safe use in foods. It believes in a continuing review of the latest evidence regarding the safety of all food components. It supports the principle of judging safety under conditions of actual use as opposed to the use of a per se doctrine. It believes that H. R. 6747, H. R. 366, and H. R. 8390 all contain desirable features which should be incorporated into such legislation.

In general, the Flavoring Extract Manufacturers' Association of the United States endorses the provisions of H. R. 6747, with the following exceptions:

1. We object to the term "chemical additive" as being misleading, inaccurate, and uninformative. All food, indeed all matter, is chemical. We feel that the bill is intended to deal primarily with new food additives; i. e., substances to be added to food which do not have a significant previous history of safe use. We feel that "new food additive" is a more accurate and less misleading term.

2. We feel that a substance, normally present as a naturally occurring food component, should have this history of safe usage considered if such a com-

ponent is proposed as an additive to other foods. We suggest the insertion of the following phrase after the word "food" in line 13, page 2, H. R. 6747: "* * * in any form and from any source," * * *.

3. We believe that it is necessary that the law provide provisional clearance for those food additives which can be shown to have enjoyed substantial usage, without objection, for a considerable period of time prior to the enactment of the proposed legislation. In any case, of course, the Food and Drug Administration should have full authority, subject to judicial review, to bar or limit the use of a food additive regardless of previous rulings applying to it if additional evidence indicates substantial question as to its safety. We would suggest, therefore, the following insertion after section 409 (a) (2): "(3) it has enjoyed substantial use for at least 5 years immediately prior to the date of enactment of this statute without objection under the Federal Food, Drug and Cosmetic Act." The Secretary may, however, bar any such previously used food additive from further use in food upon receipt of evidence from any source that the continued use of the additive would present a hazard to health. Any interested person may then petition under subsection (b) of this section for the issuance of a regulation announcing the conditions under which such an additive may safely be used.

4. We are opposed on principle to the useless addition of additives to foods. We do not believe, however, that this is a common practice, and we feel that, to the extent that it is, there are adequate legal means to cope with the situation. We do not believe that the Food and Drug Administration should be required to make a determination of functional value as a prerequisite to granting approval for use of a food additive. We believe with many others that:

(*a*) "The purposes of the food law would be fully served by limiting definitive action on food additives to the question of their safety in use."

(*b*) "The exemption from consideration of functional value of only those additives which are not poisonous or deleterious substances (sec. 409 (c) (3)) seems to retain the per se concept." We believe this concept completely at odds with reality.

(*c*) "Standardized procedures cannot be adopted to determine the usefulness of a product."

(*d*) "The determination of functional value is hardly scientific. It is probably aesthetic and inescapably economic. It ought to be answered on the grocery shelf or by the consumer in the kitchen, and not by either a Federal bureau or a learned society."

(*e*) "The whole point of this bill is to determine what is safe and what is not safe within reasonable and workable limits. We appreciate that the Food and Drug Administration must and will be conservative in determining safety. But once it has been determined that, for a particular use, an ingredient is 'without hazard to the health of man' that should be the end of the matter."

(*f*) "The American consumers are the ultimate judges and public interest lies in stimulating and encouraging technology and cooperation with the chemical industry."

(*g*) "Food preferences should not be dictated by administrative fiat."

We recommend, therefore, the elimination of that part of paragraph (3), page 8, after the word "otherwise," on line 14.

5. We believe that adequate provisions should be made for maintaining the confidential nature of much of the information that will be supplied to the Food and Drug Administration under any of the proposed legislation. We believe that the provisions of H. R. 8390, in this respect, are by far the best and should be included in H. R. 6747. We recommend the addition of a subsection (3) to section 409 (a) as follows: "the pretesting data on such additive have been fully submitted to the Secretary, and the Secretary has had an opportunity to evaluate said data in accordance with this section. The Secretary shall hold the data thus submitted in confidence, except where their disclosure is required either to protect the public health or in an enforcement proceeding under this act."

6. We believe that the provisions of H. R. 6747, with respect to the use of a Scientific Advisory Committee, are sound with one minor exception. The law should provide that any or all members of said Scientific Advisory Committee may be required to appear at later hearings. This can be accomplished by the insertion of the words "Any or all members of the Advisory Committee may be

required * * *" in lieu of the phrase "The Advisory Committee shall designate a member" on page 13, line 16.

7. We favor appeal from an administrative ruling to the district court rather than to the circuit court of appeals. We feel very strongly that the district court should be required to sustain the administrative findings of fact only when they are supported by a preponderance of the evidence; support by "substantial" evidence has come, in effect, to mean support by very little evidence at all. We have no strong preference between the declaratory judgment and injunctive procedures but tend to favor the latter.

8. We agree with the many basic principles underlying the requirements outlined in H. R. 6747 for the submission of data to the Food and Drug Administration as a means of obtaining approval for the use of a food additive. We feel, however, that certain other bills phrase these requirements in more suitable form. We believe that section 409 (b) (3), of H. R. 366 and H. R. 8390, dealing with methods of identification, analysis, and control is to be preferred. Adequate analytical methods are not available, nor likely to be available to operate with precision at the levels at which many additives are now or may be safely used. We favor the elimination of section 409 (b) (2) (C) in H. R. 6747 because many flavor compositions and components are produced in distant areas where a full description of the methods of production is unavailable and where the methods themselves are variable.

We believe that these represent the changes which the Flavoring Extract Manufacturers' Association of the United States and its membership should seek in H. R. 6747 in order that the final legislation be fair to both consumer and manufacturer and as free as possible from undue or impractical administrative requirements in its application.

Respectfully submitted,

Dr. RICHARD L. HALL,
Chairman, Food Additive Committee of Flavoring Extract Manufacturers' Association of the United States.

Approved:

MYRON J. HESS, *President.*

STATEMENT BY FREDERICK S. LEINBACH, REPRESENTING THE AMERICAN PAPER & PULP ASSOCIATION, NEW YORK, N. Y.

My name is Frederick S. Leinbach. I am executive vice president of the Riegel Paper Corp., 260 Madison Avenue, New York, N. Y. We manufacture pulp, paper, and other food packaging materials in New Jersey, North Carolina, and Indiana. I am appearing before you today on behalf of the American Paper & Pulp Association, the overall national association of the paper and pulp industry.

Ours is the fifth largest industry in the United States. It operates in 38 of those States. Along with its allied products industry, it is made up of 560,000 employees to whom at least an additional 1,6000,000 dependents look for support. The industry's payrolls are more than $2½ billion each year. In 1956, the industry's sales exceeded $10 billion. We are proud that it is a growth industry—a chemurgic industry founded upon an agricultural product. Each year sees many new users for its varied products, and all of the improvements and innovations have inured in one way or another to the benefit of the consuming public. Our progress has been directly proportional to our standard of living in this country.

The paper and pulp industry is fortunate that it does not have any problem with respect to the purity and safety of its products for use as, or in, food-packaging materials, and we wish to emphasize this at the outset. Insofar as these hearings before this subcommittee are concerned, the bills being considered deal with new food additives—and these are primarily a matter for the concern of the food industry.

The concern of the paper and pulp industry is incidental, but it is vital. The pending bills in their present form contemplate the imposition of substantial economic and administrative burdens difficult for even our largest corporations, but utterly impossible for the many small businesses among us. Even though the Food and Drug Administration always has granted the greatest cooperation to our industry with respect to continuing improvements and innovations in the food packaging, wrapping, and container fields, we have felt forced to conclude that the amendments which would be made by the pendings bills,

coupled with the prohibitions of the present section 406 (a) of the act, would in our judgment, stultify progress in sanitary food packaging by removing beyond the reach of almost all of us the accomplishments so essential to a continued improvement in the distribution of the food to the ultimate consumers.

The safety of food-packaging materials has tremendous importance to us in the paper and pulp industry because (1) it is of vital interest to public health, (2) it is of vital personal interest to the members of the paper and pulp industry because they, together with their families, comprise a substantial part of that so vitally interested public, and (3) the industry members gain a substantial portion of their livelihood through the safe packaging of foods.

Everyone in the industry agrees that there is a definite and inescapable responsibility for the manufacturers of food-packaging materials and food packages to assure the safe distribution of foods to the consumer. We believe our industry has accepted and will continue to accept that responsibility. We spend millions of dollars annually to evaluate the public health aspects of food packaging materials and their basic components, and we shall continue to do so.

Please note the statement that to bring one new pesticide to the market costs over $250,000 for toxicological research alone. For this type of material, this need not be unreasonable, for these materials are essentially poisons intended for application in the soil or to food plants during their growth and production. The health hazards involved in the manufacture and application of pesticides and their residues on foods are readily recognized. Such toxicological work is necessary for the approval of the United States Department of Agriculture and to establish tolerances of residues on food—in accordance with the pesticide law.

On the other hand, we ask your attention to the vast majority of packaging materials, for they are generally recognized among experts qualified by scientific training and experience to evaluate the safety of foods, as materials that are safe for use in food packaging, especially under the conditions of their intended use wherein they do not become and cannot reasonably be expected to become a component of the food they package. Laymen join these experts in recognizing the fact that though not intended to be eaten, these materials, with considerable confidence, can be said to be innocuous and safe, even though accidentally consumed. If there are virtually no extractables from the packaging materials as used, there should be no problem.

If there are extractables, if those materials could reasonably be expected to become a component of the packaged food, they then become additives, and we feel they should be treated as additives.

Our plea, therefore, is for that definition of the term "food additive" that will cover true food additives, but not stifle those technical advances essential to food distribution, and which enhance rather than endanger food quality.

It is our assumption that the primary concern of this subcommittee properly will be with H. R. 6747, although we recognize that there are many other bills pending before this group for your consideration. Accordingly, my remarks are directed to H. R. 6747. We would suggest that section 2 of H. R. 6747 be amended by deleting the present language of that section and substituting the following langauge defining the term "new food additive."

"SEC. 2. Section 201 of the Federal Food, Drug, and Cosmetic Act is amended by adidng at the end thereof the following new paragraphs (s), (t), and (u):

"(s) The term 'new food additive' means any substance ued or intended to be used for any purpose in the manufacture, packing, processing, preparation, or other fabrication of any food, or in the packaging, transporting, or holding of it, which (1) thus becomes or could reasonably be expected to become a component of such food and (2) is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of food, to be safe for use under the conditions of such use or intended use. The term does not include a pesticide chemical in or on a raw agricultural commodity; or, with respect to a particular food or class of foods, any substance to the extent to which, its use for general consumption in the United States in or on such food or class of foods is authorized or approved by the Food and Drug Administration or the Meat Inspection Branch of the United States Department of Agriculture, or any substance to the extent to which its use in or on a food is approved by or under this Act. Each new food additive shall be deemed a food, for the purposes of this Act.

"(t) The term 'safe for use' when used with reference to a new food additive shall mean that it is reasonably probable that such new food additive can

be used under the conditions of its intended use without rendering the food in or on which it is used injurious to health.

"(u) The term 'conditions of its intended use' when used with reference to a new food additive includes, but shall not be limited to, specifications as to the particular food or class of foods in or on which said additive is intended to be used, the quantity to be used in or on such food, and the manner in which said additive is intended to be added to or used in or on each such food."

AMERICAN PAPER & PULP ASSOCIATION,
New York, N. Y., April 15, 1958.

Hon. JOHN BELL WILLIAMS,
Chairman, Health and Science Subcommittee, House Committee on Interstate and Foreign Commerce, Washington, D. C.

DEAR MR. WILLIAMS: We respectfully submit this letter in lieu of a personal appearance before your subcommittee which is conducting hearings on bills to amend the Federal Food, Drug, and Cosmetic Act, including H. R. 10404. In August 1957. Mr. F. S. Leinbach had the privilege of submitting to you on our behalf a statement concerning H. R. 6747, and this letter explains and amends Mr. Leinbach's statement.

The pulp and paper industry on whose behalf this letter is submitted is always interested in legislation designed to protect the health, safety, and welfare of the public as a whole. As the fifth largest industry in the United States, we are not only proud of our record of growth through the development of many new products for the benefit of the consuming public, but also that ours is a chemurgic industry founded upon a basic agricultural product. The industry also takes pride in its overall record with respect to the purity and safety of its product for use as, or in, food packaging materials.

H. R. 10404 deals principally with new food additives and is therefore a matter of primary concern to the food industries. However, we are vitally interested because food-packaging materials represent today a sizable portion of the production of our industry with its almost 600,000 employees having an annual payroll of more than $2½ billion and sales exceeding $10½ billion.

Our position with respect to H. R. 10404 is one of support. We believe that the definition of the term "new food additive" is clear and is truly in the best interests of the public health and welfare. Our industry fully agrees that there is an inescapable responsibility on manufacturers of food-packaging materials and food packages to assure safe distribution of foods to consumers. We spend hundreds of thousands of dollars annually to evaluate the public health aspects of food-packaging materials and their basic components, and will continue to do so.

We therefore recommend that H. R. 10404 be favorably reported from your subcommittee without amendment and that this letter be incorporated in the transcript of the hearings.

Respectfully submitted.

ROBERT E. O'CONNOR, *Executive Secretary.*

Mr. RHODES. If there are others who wish to have their statements inserted, we would be glad to have them. We will not be able to hear all the witnesses during the day and those who cannot remain will be permitted to submit a statement.

Mr. LARRICK. Mr. Chairman, and members of the committee, my name is George P. Larrick. I am Commissioner of the Food and Drug Administration of the Department of Health, Education, and Welfare.

The number of bills that are here for consideration is evidence of the widespread interest in Congress and in the American home in the purity of the American food supply. It is gratifying indeed that so many Congressmen have taken time to study this problem and suggest methods of dealing with it.

The amount of testimony that was presented last summer is further evidence of the careful consideration that many individuals have

given to the matter. Some of my statements will present views that differ from views expressed by some industry spokesmen last year. I should emphasize that we respect the right of industry representatives to state their views even though we do not agree with all of them.

All of the bills under consideration are designed to require adequate testing of chemicals before they are added to food. There is no dispute, as far as I know, as to the need for legislation to provide assurance that the safety of chemicals has been established before they are offered for use in the Nation's diet.

One of the bills, H. R. 6747, was submitted to the Congress by the Department of Health, Education, and Welfare after the most thorough study of this important public health problem. This bill provides that a person who wishes to sponsor the use of a chemical in food must first have it tested by appropriate scientific means and submit the results of the tests to the Secretary, together with a request for a regulation specifying the conditions under which the chemical can be used safely in food. If the Department concludes from the scientific data that the proposed use is without hazard to man (or animals in case of animal feed additives), we would sanction it by publishing an appropriate regulation which would announce the permitted uses to the public as well as to the manufacturers concerned. If the chemical is not a poisonous or deleterious substance, so far as this amendment is concerned, it could be used whether or not it has any functional value. If the data show that it is a poisonous or deleterious substance, it could only be used in safe amounts and only if it has functional value.

When issued, the regulation would give all food manufacturers who might wish to use a new chemical in their foods official assurance that its safety has been established under the precise conditions set out in the regulation; the regulation would be a rule for all to follow, not a license to a single manufacturer.

The bill gives the person who proposes a regulation an opportunity to have his data and proposal reviewed by an independently selected advisory committee of expert scientists, before the Department has finally evaluated his proposal or if the Department does not agree with his proposal. The experts would be selected by the National Academy of Sciences.

If this scientific review and the recommendations of the committee fail to resolve the controversy, the person who proposed the regulation or any person adversely affected by the order could obtain a public hearing and utilize court appeal procedures that have been a part of the Federal Food, Drug, and Cosmetic Act for almost 20 years, and which are provided for in the Administrative Procedure Act, too.

Similarly, the Secretary could initiate the procedure for the issuance of a regulation specifying the conditions under which a chemical additive could be used safely in food. This could be done by publishing a proposal, with full opportunity for interested parties to be heard.

Chemicals could be exempted from meeting the detailed requirements of the bill if they were intended for research studies to determine their safety or if it were found that for other reasons such an exemption was entirely consistent with protection of the public health.

The bill would not apply to chemicals that are generally recognized

as safe by qualified experts, either on the basis of appropriate scientific studies or prolonged food use. It would not apply to chemical additive uses already shown to be safe to the satisfaction of the Food and Drug Administration or, in the case of uses in meat food products, to the satisfaction of the Meat Inspection Division of the Department of Agriculture. This is the modified grandfather clause of the bill.

May I now explain in some detail the solution H. R. 6747 presents for three important questions. These are:

1. Its modified grandfather clause;
2. Its treatment of the functional value or usefulness question; and
3. The control proposed for chemicals that may cause cancer.

THE GRANDFATHER CLAUSE

Some proposals have been made that, in effect, would consider all additives in use when the law is enacted to be safe. For example one witness testified:

> * * * we urge the adoption of an adequate grandfather clause which would provide that all food additives, in use at the time the new law becomes effective, would continue to be policed under the old law until and unless a regulation respecting the use of such additives is issued pursuant to the provisions of the new law.

We think this would not afford adequate protection of the public health, because the manufacturer who had already marketed an additive without adequately testing it would have no more obligation to test it and obtain clearance under new legislation with this provision than he felt under the old law and because the Food and Drug Administration with its limited facilities could not test all of the chemicals as promptly as is desirable.

The Department's bill does not propose to rule old additives off the market preemptorily. It would allow an old additive, not generally recognized as safe, up to 18 months from the date of enactment to meet necessary safety clearance procedures, and it would allow the Secretary to extend this time for up to another 12 months when that could be done without undue risk to the public health. This is a total of 2½ years, which we believe should be sufficient for any additive that is safe enough to pass the basic testing procedures accepted by responsible scientists.

FUNCTIONAL VALUE

Several witnesses have objected to the requirement in H. R. 6747 that if an additive is poisonous or deleterious, it must have functional value before it is allowed in food. They evidently believe that functional value bears no relation to safety, and that the values or usefulness of such an additive should be determined only by the manufacturer. As one witness expressed it, "Value is to be determined in the market place and not by administrative decision."

But these witnesses have overlooked the important fact, that functional value (or usefulness to the consumer) is a vital safety factor. The purposeless addition of toxic chemicals to food, even if the practice seems a safe one, is not a sound pure food policy. Remember that the panel of scientists testified here that there is no known way to establish the absolute safety of an additive. We can establish its safety beyond a reasonable doubt, in the light of current scientific

knowledge, but having done this we should be sure that the use of the chemical, if it be poisonous or deleterious, yields some benefit to the consumer.

The addition of excessive amounts of poisonous materials is not a sound pure food policy either.

If one-tenth percent of a poisonous additive accomplishes the desired purpose, it would be unwise to lessen the safety factor by permitting 1 percent of it. The Expert Committee on Food Additives sponsored jointly by the Food and Agriculture Organization of the United Nations and by the World Health Organization concluded at its meeting in December 1956, "The amount of an authorized additive used in food should be the minimum necessary to produce the desired effect." We agree with this basic principle.

In establishing pesticide tolerances under the recently enacted Federal law, we have found on several occasions that the tolerance level requested by a petitioner is higher than needed for useful employment of the chemical. Where this is true, we set the tolerance at the safe level that will accomplish the purpose without loading the food supply unnecessarily. For example, we were asked to establish a tolerance of 23 parts per million for the antibiotic chlortetracycline in uncooked poultry; this might have been safe, but 7 parts per million was adequate and the tolerance was put at the lower figure. We were asked to exempt the preservative, diphenyl, from the requirement of a tolerance on certain citrus fruits. The exemption might have been safe, but a tolerance of 110 parts per million was adequate and was established in lieu of the exemption.

If the Department is to restrict the purposeless addition of poisons, it must have the authority to prohibit their addition to food at levels higher than those needed to contribute the functional value sought.

What is this functional value we have been discussing? We think it is something that benefits the consumer directly in terms of product improvement or food convenience, or indirectly in terms of improvement in food processing, storage, packing, or other steps in moving the food from its raw state to the dinner table. It follows that it is something of benefit to the manufacturer, too.

But to make the definition clear, there are uses that in our view would not have functional value. They are uses that would disguise faulty processing and handling techniques, uses that would deceive the consumer, and uses that would result in a substantial reduction in the nutritive value of food. I have attached to my prepared statement and ask permission to have included in the record a partial list of chemical uses that have been employed in the past and which are not used today which would not meet the test of functional value.

(The information referred to follows:)

PARTIAL LIST OF CHEMICAL ADDITIVE USES THAT WOULD NOT HAVE FUNCTIONAL VALUE

Borates (boric acid or borax) in codfish and whole eggs as preservatives (to mask poor manufacturing or storage practices).

Chrome yellow on coffee beans for coloring (to make the beans appear to be of better value).

Copper in canned peas for coloring (to make the peas appear to be less mature).

Fluorine compounds in beer and wine to stop fermentation (as a substitute for the pasteurization used in good manufacture).

Formaldehyde in milk to kill bacteria, or in frozen eggs to conceal the odor of decomposition (to mask poor production or storage practices).

Hydrogen peroxide in cream and milk as a preservative (to mask poor production or storage practices).

Monochloracetic acid in various foods, such as carbonated and fruit-type beverages, pickles, and wine (to replace proper sanitation).

Salicylates in shrimp sauce (to retard decomposition from poor manufacturing or holding practices).

Sodium nitrite in fish fillets (as a preservative in lieu of good manufacturing and handling practices).

Sulfites (to redden stale meat).

Mr. LARRICK. To mention two for illustration:

1. The use of formaldehyde in milk to cover up poor sanitary practices.

2. The use of sulfites to redden stale meat.

These and the other uses on the list have been employed in the past. They have required legal actions by various Government agencies. And if legislation were passed without the functional-value provision or an equivalent, we would be forced, upon a showing of safety, to turn back the calendar 50 years and set tolerances for the notorious old adulterants, such as formaldehyde for milk and sulfites for meat. These are additives that contributed to scandals that brought about enactment of the original Food and Drug Act and the Meat Inspection Act in 1906. Then having set the tolerances we would be obliged to try to prevent illegal uses of the adulterants where possible under other sections of the law. A law is hardly a good law if it apparently permits under one section practices that are illegal under other sections.

It seems evident to us that the public welfare demands some supervision of a manufacturer's unilaterial determination that there is a reason for using a poisonous chemical additive. The play of the market place must not be the sole criterion in this field where the public health is at stake. We must have a law that will cope with the type of manufacturer who does not appear before your committee, the ruthless producer who will stop at nothing to make a fast dollar. Although they are distinctly in the minority, they do have to be controlled.

The functional value provision of the Department's bill, H. R. 6747, is a relaxation of existing law. The present law provides that tolerances may be established for added poisonous or deleterious substances in food only when they are required in its production or cannot be avoided by good manufacturing practice, a far more stringent criterion than the proposed functional value requirement. And our Department today determines in the first instance whether these substances are so required or unavoidable. The law does not now leave the decision to business when a known poison is involved. In lieu of this stringent requirement of necessity, we have proposed in H. R. 6747 to substitute what we believe is the reasonable requirement of functional value. In our view we can go no farther without sacrificing essential public-health safeguards.

I have attached to my prepared statement, and ask permission to have included in the record, a copy of a paper by Mr. William W. Goodrich, Assistant General Counsel for Food and Drugs, entitled, "The Rational Use of Chemicals in Foods." It gives a more detailed discussion of the functional value question.

(The information referred to follows:)

THE RATIONAL USE OF CHEMICALS IN FOOD

By William W. Goodrich, Assistant General Counsel for Food and Drugs, United States Department of Health, Education, and Welfare, Washington D. C.

Since Dr. Wiley's time, the Food and Drug Administration has been concerned with the problem of chemicals in food. Perhaps Dr. Wiley's greatest contribution—aside from the task of attracting the needed public attention which brought the Food and Drugs Act of 1906 into being—was to study, expose, and eliminate some of the more obvious poisons from foods.

Dr. Wiley was concerned with poisons in the crudest sense of the word; with formaldehyde in milk, cocaine in sofe drinks, poisonous preservatives in tomato catsup, toxic substances in meats, etc. He pioneered with ways to demonstrate the harmful effects of these poisons, and he dramatized his efforts through his famous poisons squad.

Today, the facilities and personnel of the Administration are hard at work with the same problem in modern dress; not so much with the acute poisons that result in immediate harm and can readily be identified, but with the more insidious longtime toxic effects of small daily amounts of food chemicals.

And Congress is considering new legislation which at once would relax the longstanding prohibition against unnecessary and avoidable poisons and deleterious substances in food and would permit the use of safe amounts of any new chemical.

Nothing in the proposed legislation has stirred greater attention among the food and chemical industries—except perhaps the question of judicial control—than the Administration's proposal that new chemicals that are poisonous or deleterious substances must be safe for their intended use and must have some functional value in that intended use.

I would like to discuss with you the significance of the change of national food policy contemplated by this new legislation.

The 1906 act prohibited any added poisonous or other deleterious substance which may render a food injurious to health.

The Coca-Cola case established that all ingredients of a fabricated food are added substances, in the statutory sense. And the Lexington Mill & Elevator decision ruled that "may render the food injurious to health" meant precisely what it said: if any added poisonous or other deleterious ingredient in a food may possibly injure the health of any consumer of the food—the strong or the weak, the old or the young, the well or the sick—the food was adulterated.

But despite these strongly worded Supreme Court decisions, the fact remained that each food had to be considered separately. Unless the amount of the added poisonous or other deleterious ingredient was enough in each food to render that particular food injurious, no ban was placed upon it.

That other items in the diet might contribute some of the same substance, or a related poisonous or deleterious substance, could not be considered.

This great weakness was seen in practice, and Congress undertook to eliminate it by enactment of the 1938 law.

The new statute included the so-called per se rule against all unnecessary and avoidable poisonous and deleterious substances added to foods. It provided that when poisonous or deleterious substances were required in the production of a food or could not be avoided in good manufacturing practice, the Department should establish safe tolerances for them.

We were clearly authorized to take into account the extent to which the chemical was required or unavoidable, and the several ways the consumer may be affected by the same or any other poisonous or deleterious substance.

The rule of reason established by the existing law was founded on great caution and a very strong public prejudice against chemicals. The answer to any proposed use of a poisonous or deleterious substance was an emphatic "No," unless it could be shown that the chemical was required or unavoidable.

And over the years, only the insecticidal, fungicidal, and other agricultural chemicals met this strict test. No tolerance has ever been established for any other kind of poisonous substance. Even in the case of the insecticidal sprays—which Congress plainly indicated it intended to permit under the per se rule—literal reading of the statute would have made it difficult to justify a variety of agricultural chemicals with different degrees of toxicity, all intended to attack the same agricultural pests.

In 1954, Congress passed special legislation on the pesticide chemicals, and substituted for the required-in-production test, the test of agricultural usefulness as determined by the Secretary of Agriculture.

Unless some rational agricultural utility can first be shown, we are relieved from considering the question of tolerances. And in considering agricultural usefulness, the Secretary of Agriculture must tell us how much residue is likely to remain when the pesticide is used to accomplish the desired agricultural purpose.

We do not tolerate residues of pesticide chemicals above the levels needed in rational agriculture. National policy there has been to permit what is needed if that amount can be shown safe. If the amount cannot be shown safe, we need not tolerate it despite its established usefulness. Higher amounts need not be tolerated, even though apparently safe, if there is no sound agricultural reason to use the higher levels.

In brief, if 7 parts per million of a pesticide is all that is needed for sound agricultural practices, we fix the tolerance at 7, though 20 parts per million might be considered safe. Lacking a reason for a higher tolerance, there is no point in tolerating the excess poisonous residues, however slight the risk involved.

As to all other added poisonous or deleterious substances in food, the per se rule of exclusion still prevails. Over the years no chemicals met this test. In the early forty's, proposals, were made to us to establish a tolerance for monochloracetic acid in wine. This chemical has a toxicity comparable to bichloride of mercury.

The proponents of the tolerance proposed the use to prevent fermentation of certain sweet wines. They represented that the chemical would prevent spoilage and the consequent economic loss. They were told frankly that the Food and Drug Administration would not consider this use one that is "required in production," because wine had been produced for generations without a preservative and proper sanitary measures in production and handling would make chemical preservation unnecessary. The petition was, nonetheless, scheduled for a hearing, but was withdrawn when the industry was unable to get ready by the assigned date.

The matter was dropped, and a number of regulatory actions were taken against foods—beverage bases, mayonnaise, etc., containing this chemical. About the same time, the Commonwealth Brewing case was tried, with jury instructions to the effect that any amount of fluorides to be a poisonous or deleterious substance that was not required in production or was avoidable in good manufacturing practice.

The evidence for the Government compared the fluorides to well-known acute poisons, and showed that beer had been produced for generations without the chemical. Somewhat later, a chemical manufacturer proposed the use of dimethyl dichlorosuccinate as a mold inhibitor on cheese wrappers. The petition was rejected because the evidence in the petition showed the chemical to be a poisonous substance.

"Required in production" could not be established because wrapped cheeses without antimycotics were in widespread production and sale. Recently, two proposals have been advanced to establish a tolerance for a poisonous antioxidant in dehydrated alfalfa and a poisonous sprout inhibitor for potatoes and onions. In these cases it seemed fairly clear that the chemicals served an agriculturally useful antioxidant.

While these chemicals are still under consideration, they have not yet been shown to meet the strict rule of exclusion of unnecessary and avoidable poisons.

Some of the proposed bills on chemicals in foods would scrap the per se tests as the rule of reason in permitting poisons. The industry-supported proposals in the last session of Congress would go the whole circle back to the point where any chemical—even a notorious poison such as formaldehyde—could be added to any food for any real or fanciful reason, or for no reason at all.

They would say that so long as the proposed level of use of formaldehyde involved no health hazard, it is none of the Department's business why the proponent of the chemical wants it used. The argument is that if safety is shown that is all that is needed; that business considerations will be enough to sell the chemical or to prevent its sale.

The Food and Drug Administration's files are full of evidence that this philosophy is not acceptable to the average consumer. The public doesn't support the purposeless addition of chemicals to its foods. Yet we believe it does support the rational use of chemicals to simplify food processing and to improve the food

supply. It wants only the assurance that there is a good reason for the addition of the chemical and that the chemical in the diet is safe.

Our correspondents will not accept the idea that we should allow the indiscriminate use of small amounts of known poisons in our foods only because on the basis of tests with laboratory animals these small amounts appear to be safe. They want to know what justification there is for using the chemical; not that there is no positive reason for not using it.

There is reason enough for not using it if it is a poisonous substance. Public opinion will be satisfied only by a rational justification based on considerations of food technology or consumer benefit coupled with assurance of safety of the proposed use.

So much for the public attitudes as they are reflected to us by our consumer contacts. These attitudes find support among the scientists and public health officials concerned with the problem of chemicals in foods.

These scientists, in the most solemn statement of policy on the factors to be considered in permitting the addition of chemicals to our foods, have said that the proposed use of the chemical must be both safe and beneficial to the consumer. They explain this by saying that we cannot be sure—using present-day methods of safety testing—that a proposed use of a chemical will be absolutely safe.

Our methods do give us an assurance of safety which removes all reasonable doubts. There remains, however, a gap between reasonable doubt and absolute certainty which science cannot close. Because of that, the Food Protection Committee has said that a chemical substance should not be added, even though its safety is shown by the best available scientific means, unless the chemical is also beneficial to the consumer.

This is a philosophy with which food officials and our scientific advisers agree. We interpret "beneficial to the consumer" to mean a use which benefits him, directly, in terms of product improvement or food convenience, or, indirectly, in terms of improvement in food processing, storage, packing, or other steps in moving the food from its raw state to the dinner table.

To us, that is what is meant by "functional value," as the term is used in the Department-sponsored bill. We are willing to accept the idea that the reason for adding a chemical is none of our business under this law when the chemical is an innocuous one, but we cannot accept the idea of the pointless addition of poisonous or deleterious substances to our food.

We do not think it out of line to ask why the chemical is proposed when the scientific data shows it to be a poison. We cannot believe that any reasonable food manufacturer would not ask himself "Why?" before he added a poison to his products. And we are certain that the consumer would want to know why.

In our thinking, the reason for the proposed use is a relevant factor in permitting the chemical so long as scientific methods do not provide absolute assurance of safety.

Why not continue with the "required in production" and "unavoidable in good manufacturing practice" test? Because this test is not realistic; few, if any, chemicals can meet it when it is applied as written; and because it needlessly prevents the use of technologically important food chemicals at levels as to which there is no reasonable doubt of safety.

The Department's bill was drawn to provide a rational basis for the use of chemicals in foods that could be accepted by food manufacturers, chemical manufacturers, scientists, and consumers alike as a proper rule under which food technology may progress without endangering the public health.

The none-of-your-business approach is unacceptable to scientists, to consumers, and to public-health officials. We believe it equally unacceptable to responsible business people.

Mr. LARRICK. Two of the bills before you make specific mention of cancer. The others, including H. R. 6747, do not mention it specifically. Your subcommittee has a letter dated July 22, 1957, from the American Cancer Society, Inc., which recommends that legislation on chemical additives embrace three principles. We endorse the society's goal of seeing that cancer-producing foods are not on the American market. This was one of the Department's cardinal aims in drafting H. R. 6747. This bill bars the use of an additive unless it is established that it is without hazard to health. Thus, the bill would prohibit the addition of any chemical additive to the food

supply until adequate evidence, acceptable to competent scientists, shows that it will not produce cancer in man under the conditions of use proposed.

But we see no more reason to single out cancer production for specific mention in the legislation than to single out production of high blood pressure, destruction of the blood-forming elements of the body, or production of nephritis, diabetes, or a host of other disorders. All of these things are of extreme importance. We, certainly, do not intend to sanction a chemical additive in the food supply unless the evidence rules out any reasonable ground for believing that the proposed use will constitute a hazard to the public health in any respect.

IRRADIATION OF FOOD

H. R. 6747 was intended to require adequate safety testing before commercial marketing of all foods sterilized, pasteurized, or otherwise treated with ionizing radiations. This is needed because such radiations can and do cause changes in essential food nutrients, and the safety of the treated food for long-term consumption has not been established. As submitted to you, the bill would cover radioisotopes from nuclear reactors, but there is some doubt that it would cover X-ray machines and newer particle accelerators. The energy from these machines can produce the same kinds of changes as the energy from radioisotopes; the machines are being considered for use in food processing. Therefore, the Secretary has written your committee, suggesting two perfecting amendments to H. R. 6747. These would subject X-ray machines and other particle accelerators to the same control as is proposed for radioisotopes, and would declare irradiated food to be adulterated unless the irradiation were performed in conformity with a regulation or exemption in effect under the chemical additives amendment. These changes would give assurance of the full control over commercial use of ionizing radiations in food production that was intended when H. R. 6747 was originally drafted. We have discussed this matter with the Atomic Energy Commission, which agrees with us that the perfecting amendments are proper.

There are a number of other matters that warrant attention, but I will not take your time to discuss them in detail here. They are covered in the Secretary's letters to Chairman Harris about the individual bills under consideration, or in a separate memorandum attached to my prepared statement, which I ask leave to have included in the record following this statement. In particular, I call your attention to our comments on the provision in some bills and the suggestions in some testimony that an additive be judged safe if it is reasonably probable that it will not be a hazard to health or that it will not render food injurious to health. In our view, the public health cannot be adequately protected with such a provision. Also, I direct your attention to the administrative and judicial-review procedures which have been discussed by Assistant Secretary Elliot L. Richardson, and to the discussion of the procedure for referring difficult questions of science to an advisory committee of experts selected by the National Academy of Sciences.

One further point that deserves attention is the need for the Federal Government to take the lead in this important matter and enact legisltaion that will serve as a guide to the States and cities and en-

courage the adoption of reasonably uniform laws. We need all the help they can give in controlling chemical additives, for the task is so big that combined Federal-State-city interest is imperative.

Last year the State of Utah enacted a new food, drug, and cosmetic law that contains an approach to the control of chemical additives not too different from the basic principles in some of the bills you are considering. The State of New York is considering new additives legislation now. New York City is considering a revision of its sanitary code with respect to food additives. And we understand that food-law enforcement officials of other States are considering the steps they should take to deal with residues of additives. If the Federal Government fails to enact legislation that can serve as a guide, the result may be the adoption of varying methods of State and local control.

In conclusion, the problem, the real hazard of the use of inadequately tested chemicals in food is very clear and is with us today. It is not, as some of the testimony last summer suggested, merely a theoretical problem. Inadequately tested chemicals are being used in food today and their use constitutes a real hazard to the public health.

(The information referred to follows:)

SUPPLEMENTAL STATEMENT OF THE DEPARTMENT'S VIEWS TO ACCOMPANY STATEMENT OF GEORGE P. LARRICK ON CHEMICAL ADDITIVES LEGISLATION

1. SCOPE OF THE LEGISLATION

(a) *Definition of "chemical additive"*

The witness for the Grocery Manufacturers Association questions the definition of "chemical additive" suggested in the administration bill. He states:

"The food additive definition under review is principally obscure, because of its governing 'generally recognized' clause."

The so-called generally recognized clause here referred to is the provision (p. 2, lines 8–14) under which a substance which otherwise would be regarded as a chemical additive is nevertheless to be considered as such only if—"not generally recognized among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures or through prolonged use in food to be safe for use under the conditions of its intended use."

All the bills, including those supported by industry, contain a "generally recognized" clause in one form or another. It stems from the similar provisions of the Federal Food, Drug, and Cosmetic Act with respect to new drugs (sec. 201 (p) and pesticide chemicals (sec. 409)).

The clause is designed to exclude from the bills those substances which according to the general consensus of competent scientific opinion are safe under the conditions of their intended use. While in all the bills this exclusionary provision is an integral though negative part of the basic definition, it could with the same effect, and no less logic, have been placed in section 409 (a)—in analogy to section 408 of the present act—which states under what circumstances a chemical additive shall be deemed to be unsafe. It is important to note that under all the bills, as drawn, the burden would be on the Government, in an enforcement proceeding, to prove that a substance is not generally recognized by experts as safe and is therefore within the scope of the bill.

The concept of scientific consensus is, to be sure, not susceptible of reduction to a mathematical formula, but it is not obscure as a governing rule. Neither the industry nor the Government has encountered any material difficulty in determining under the present act whether new drugs or pesticide chemicals are generally recognized by appropriately qualified experts as safe.

At any rate—assuming that (in addition to the Secretary's exempting authority) some provision is desirable for automatically excluding from the bill those additives which may safely be used without submission for official safety evalua-

tion—no one, as yet, has been able to devise a satisfactory substitute for the "generally accepted" concept, and the revised definition offered by the witness again contains a "generally recognized" clause.

It is therefore puzzling to note that testimony that "the committee study the question whether such definition should not be soundly and fairly revised accordingly."

The witness for National Canners Association concludes that the definition in H. R. 6747 might cover additives accidentally incorporated in food. The bill is not intended to cover accidental contamination.

(*b*) *Definition of the expression "safe for use"*

Some witnesses suggest that the expression "safe for use" be defined to mean that a chemical additive is safe when it is reasonably probable that it can be used under the conditions of its intended use without rendering the food in or on which it is used injurious to health.

Perhaps this stems from the philosophy of the drug section of the law. When a chemical to be consumed by man is a therapeutic agent, the appraisal of toxicological data frequently becomes a decision between two threats to health; the hazard of no treatment versus the risk involved in treatment. Under such circumstances it is quite proper to tolerate a drug even though some risk is attached to its use if the benefits from using it far outweigh its hazards. But as the justification for use becomes less apparent, it is proper to increase the margin of safety.

Ultimately we reach the dividing line between chemicals that are therapeutic agents and those that are proposed for use in food. When we reach this point, the exercise of conservative judgment requires demonstration of even greater safety. Drug use may be for a short time and under close medical supervision, but when the chemical is added to food it may be consumed for a lifetime, by the sick and the healthy, and without medical supervision.

We do not want to feed chemically treated food to our children if the only assurance we have is that it is reasonably probable that the added chemicals will not cause harm. We want to know that it has been established convincingly that the added chemicals will not harm the youngsters and we believe the average mother in the United States today wants and deserves that same assurance. We think it would be poor public health protection to allow poisons in food solely on a showing that it is reasonably probable that they will not cause trouble.

c. Should chemical additives be considered food?

The statement submitted on behalf of the Society of the Plastics Industry, Inc., further questions the propriety of the provision, contained in most of the bills, which expressly deems an additive covered by the proposed legislation to be a "food" within the meaning of the basic act, whether or not it would be so considered in the absence of that provisions (see e. g., sec. 3 of H. R. 6767).

Already, section 201 (f) of the Federal Food, Drug, and Cosmetic Act defines "food" to mean "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Many "natural" food additives, such as sugar and salt, are, of course, "foods" under section 201 (f) (1) even before they are used as additives.

Further, under clause (3) any substances intended as food additives, even before actually being introduced into or onto the food, would seem clearly to be classed as "food" for all the purposes of the act, even though they may at that stage not fit under clause (1). The purpose of clause (3), of course, is to subject all intentional additives, as soon as offered for introduction into interstate commerce, to all the act's requirements for food, so that substances intended for use in or on food will be clean, harmless, properly labeled, etc., before being put to their intended use.

To defer regulation of such substances until they are actually used in or on food and the food is introduced into interstate commerce would, among other things, render much more difficult the task of enforcement with respect to food contaminated by unsafe or unclear additives and would deprive manufacturers, processors, restaurants, hospitals, and housewives buying additives for use in or on food of such assurance as the law gives that what they are buying is not misrepresented, is clean, and may be safely used.

It is not so clear, however, whether a substance which is not intended to be "used for a component" of food, but which, as in the case of a migratory component of food packaging material, may be reason of its use foreseeably find its way into food, is itself "food" within the meaning of section 201 (f) (3) of the present act.

The purpose of the provision of the present bills which deems all additives covered by the bills to be "food" is to dispel this doubt and to make clear beyond peradventure that any additive covered by the bill and not exempted from it must comply with the pretesting safety requirements of the bills at the time of entering interstate commerce and must not be adulterated or misbranded while in such commerce or thereafter.

There is as much need for this in the case of these foreseeable but nondeliberate components of food as in the case of substances deliberately intended as such components.

The statement for Society of the Plastics Industry adduces two arguments against this provision. In the first place, it argues that chemical additives, and especially migratory components of food packaging materials, should not themselves be classed as food because pesticide chemicals are not, before they are applied to raw agricultural commodities.

Even if we assume that this is true of pesticide chemicals intended for raw agricultural commodities, the analogy does not hold, for it overlooks the fact that pesticides are subjected to close formula and label supervision under a registration law (the Federal Insecticide, Fungicide, and Rodenticide Act) administered by the Department of Agriculture, and that in the case of a pesticide intended for use on raw agricultural commodities that Department has announced that it will withhold registration until we have granted a tolerance or exemption.

Food-packaging components, on the other hand, are not in general subject to such control under another law. Thus migratory packaging components need to be controlled under the Federal Food, Drug, and Cosmetic Act to insure that when shipped in interstate commerce they are adequately labeled, pretested for safety, and otherwise in compliance wih relevant provisions of the act. Failure to provide such control would mean that in case of violation we could act only after food became contaminated by the packaging component.

H. R. 6747 and, less effectively, most other bills, would permit action against the violative component before it becomes a part of the packaged food.

The second argument made against this provision of the bills is that it would indiscriminately—the statement uses the word "indelicately"—apply to additives, and in particular to packaging materials, all the provisions of the act applying to food which were never written with that purpose in mind. As an alternative, the statement suggests "rewriting the enforcement mechanism" (without saying how) or adding to section 201 (f) (4) of the present act the following:

"Chemical additives shall be deemed to be food for the purposes of sections 401 (a) (1), 402 (a) (2), 301 (a), 301 (c), 302, and 304."

The purpose of the latter suggestion for amendment is not clear, though it does seem intended to permit the Government to proceed against a chemical additive or its shipper even before its actual use in connection with food.

At any rate, apart from other objections to it, the draft amendment would be retrogressive in that it would for most purposes declassify as "food" those intentional additives covered by the bill which (as above stated) are already "food" within the meaning of section 201 (f) (3) of the act even though they are not suited to be eaten or drunk except as a component of food.

(d) Status of meat and food derived from animals

The witness for the Grocery Manufacturers Association has suggested that the chemical additives amendment should not apply to meat and meat food products because they are regulated by the Federal Meat Inspection Act. The regulation of meat under the Federal Meat Inspection Act occurs in the inspected establishment. The Federal Government under that act does not have jurisdiction over meat that has left the inspected establishment and it has been necessary under the provisions of the Food, Drug, and Cosmetic Act upon occasion to apprehend and remove from the market shipments of meat that is found unfit after leaving the inspected establishment.

It would be unwise, we think, to establish a loophole in the chemical additives amendment whereby meat products that are unfit after leaving a federally inspected establishment, because of the addition of poisonous chemicals, would be outside the scope of a Federal law.

Additionally, packaging components for use in special meat wraps need the same sort of premarketing clearance as packaging components for use on other foods.

The setting of tolerances for chemical residues in meat has already been covered in part in the pesticide chemicals amendment of the Federal Food, Drug, and Cosmetic Act; under that amendment FDA establishes safe tolerances for pesticide residues in meat, just as it would establish safe tolerances for other additives under H. R. 6747.

We have discussed this procedure with the Department of Agriculture, and it agrees with us that the establishment of tolerances is peculiarly a problem for the Department of Health, Education, and Welfare. This does not mean, however, that there will be a duplication of effort by the two agencies. As we envisage the operation of the statute, and as we have discussed it with the Department of Agriculture, the tolerance would be fixed by FDA after consultation with the Meat Inspection Division of that Department, and Meat Inspection Division would have procedures for detecting unsafe residues in meats, and withholding the stamp of approval from meats with excessive residues. However, if meats with excessive residues should not be detected in the inspected establishment, there would be authority to remove them from the market by seizure in order to protect the public health.

The same witness recommends that H. R. 6747 be further revised to eliminate its reference to a "food additive derived from an animal." It is apparent from the testimony that he intended to refer to "food yielded by or derived from an animal" as the expression is used in section 409 (c) (3) of the bill.

The purpose of including this statement in the bill is to make it perfectly clear that the Department is to consider safety of additives broadly and not narrowly. For example, a chemical added to poultry feed to retard the destruction of certain vitamins was found in eggs from flocks consuming the feed. Testing of this chemical showed that it had serious effects on the reproduction of rats and we got its use in poultry feed stopped, not because of any evidence that it would be harmful to the poultry but because the safety of eggs from treated poultry had not been established.

Had the proposal now under consideration been a part of the law, we might have been barred from eliminating this poisonous antioxidant from poultry feed.

It is a well-known fact that numerous substances fed to dairy animals carry through into the milk from these animals. For over 50 years we have maintained the policy that milk should not contain poisonous chemicals and an advisory committee of outstanding scientists selected by the National Research Council has just endorsed the soundness of this policy.

But under the change suggested by the witness, the Government would abandon the progress achieved under this policy and would have to close its eyes to the possibility that chemicals in animal feeds might carry through into the milk supply of the Nation with undersirable effects upon all of those who consume milk as a major part of their diet.

Similarly, chemicals fed to animals may show up in meat and other edible products. It is essential for adequate public health protection that the Department have the right when considering chemicals proposed for use in an animal feed to consider not only the health of the animal consuming the chemical but also the safety of the human whose food is derived from the animal.

(e) *Should a chemical be exempt from coverage of the bill because of an alleged "informal" sanction?*

The witness for the National Canners Association proposed that the legislation not apply to any substance used in accordance with a sanction or approval, "formal or informal," shown to have been granted prior to the enactment of the bill. In his testimony he explains that the word informal is included because many manufacturers have inquired about the propriety of using a particular ingredient, have often been told informally that such use was proper, and have not bothered to get a formal letter.

Our observation has been that the businessmen with whom we deal have not generally operated in such a cavalier fashion. Our experience is that those who consult us about additives ordinarily request written confirmation where we have agreed that an additive may safely be incorporated in food.

Whether or not confirmation is requested by industry, it is standard procedure within the Food and Drug Administration to make a written record of discussions that take place with industry representatives and keep such record in our files.

Orderly administration and reasonable consumer protection both demand that chemicals not be exempted from the provisions of the bill because of alleged prior approval unless there is a written record of the approval. In a matter involving

the public health, as this bill does, the question as to whether an additive is to be included or excluded from the scope of the bill cannot safely be resolved on the basis of recollection, even the most honest recollection, of witnesses unsupported by the written records which are routine in FDA's conduct of its affairs.

Clearly, prior approval of an additive's use, which exempts it from coverage under the bill, should be a matter of written record.

2. TESTING AND EVALUATION

(a) *Should the amendment specify the scientific procedures to be used in testing for safety?*

The witness for the Grocery Manufacturers of America recommended that the bill should provide for administrative publication of the scientific procedures to be used by industry in determining the safety of an additive. This recommendation was opposed by members of the scientific panel. The Food and Drug Administration agrees that a fixed set of uniform test procedures which are prescribed and obligatory would serve effectively to slow down progress in the development of more effective procedures and methods. We agree with the scientists that the scientist working in this field and utilizing his training and experience should be able to design for each proposed additive the research program which will be most likely to yield helpful information.

(b) *Should some additives be presumed to be harmless and thus be relieved of the testing requirements?*

The witness for the Manufacturing Chemists Association testified that food additives should be given the presumption of harmlessness, and the harmfulness of them should be proven. And the statement of the Society of the Plastics Industry, Inc., holds it "unwarranted to contend that new packaging components should be considered prima facie unsafe."

These suggestions get to the basic question that has prompted the consideration of chemical additives legislation for several years:

Should chemicals whose safety for their intended use has not been clearly established be tested and proved safe before they are permitted in food?

The Department agrees with the overwhelming body of testimony last summer that additives should be tested in advance and used only if thus shown to be safe. To consider additives "harmless" or prima facie "safe" would amount to considering them suitable for use in food without testing.

Even the packaging components which may get into food in minute amount should be tested to determine whether they do migrate into food, and if they do, whether the quantity that migrates is safe. Some of the most insidious poisons have an adverse effect in minute amount. Mercury compounds, for example, are so poisonous to the animal body that we do not know of any benefit that would justify their incorporation in food in any concentration, whether they got in by direct addition or by migration from packaging materials.

3. PROCEDURE

(a) *Should the manufacturer have to state reasonable grounds for an additive regulation when petitioning for a new regulation to permit a new additive?*

The witness for the Grocery Manufacturers of America objected to the requirement in the administration bill that the manufacturer should state reasonable grounds for the regulation he requests.

We are unable to follow the logic of the objection. If a request for approval of an additive's use is not reasonable, the Department should not be expected to devote its time to it. If the proposal is reasonable, the petitioner should have no difficulty in stating the grounds that establish its reasonableness.

(b) *Should the manufacturer be given an administrative hearing before a regulation issues on his chemical additive?*

The witness for the Grocery Manufacturers of America recommends that the bill grant an administrative hearing to a manufacturer proposing a food additive regulation before the regulation becomes effective. We presume that this contemplates a hearing of record for if the hearing were not of record, it would have no evidential value in later appeal proceedings which the manufacturer might decide to undertake.

It is difficult to see the value of such an added appeal procedure. Under H. R. 6747, the scientists of the Department would consider all of the evidence avail-

able on a petition for a chemical additive regulation. If the manufacturer failed to submit all of the evidence in his possession, he could complete the application by submitting the additional data in writing. To submit it by formal hearing procedure would require the presence of a hearing officer and of representatives of the various interested units of the Department.

It would complicate materially the efficient administration of the act without giving any genuine benefit either to the Government or the petitioner.

(c) Should the Government hold the scientific data submitted to support a request for approval of an additive in confidence?

The witness for the Grocery Manufacturers Association testified that the Government should hold such data in confidence except where their disclosure is required either to protect the public health or in an enforcement proceeding under the Federal Drug and Cosmetic Act.

Dr. Henry F. Smyth, Jr., a member of the scientific panel, recommended to the subcommittee by letter that the scientific evidence for safety of the use of a new food additive should be published in the scientific literature before the additive reaches the country's food supply.

The Department can operate successfully either under a requirement of secrecy or under a provision for publicity. We would prefer to have the privilege of making scientific safety data publicly available at the time a regulation permitting a new chemical additive use is published. We think it is a sound public health policy to open such data for scrutiny by competent scientists throughout the world.

We question the necessity, however, of delaying the issuance of a regulation until such data have been published in the scientific literature. There may be considerable delay between the time the evidence is available and the time a scientific journal is able to publish it. It would be unfortunate if the use of a very desirable additive had to be held up for a matter of months solely because of this.

(d) Should there be an advisory committee procedure?

The advisory committee procedure in H. R. 6747 was proposed in an effort to give industry the same opportunity of getting a scientific question reviewed by an independent group of recognized scientists that the Department now has. Under it, if a manufacturer believed the Department's decision were in error, he should call for a panel of experts selected by the National Academy of Sciences. The panel would review available data, and submit a report and recommendations to the Department, which would issue a new order.

Plainly the Department would give great weight to the views of such a group on a scientific question.

We have always had the opportunity of consulting the National Academy of Sciences on scientific questions. The Academy was established to advise the Government on such matters. We are willing for industry to have the same opportunity.

Mr. WILLIAMS. Thank you, Mr. Larrick.

Mr. Dingell.

Mr. DINGELL. Mr. Larrick, I would like to compliment you on the very fine statement and the splendid job you have done as Commissioner of the Food and Drug Administration. As you recall, when I was discussing the matter with the Secretary, I was mainly interested in the problem of the grandfather clause. I would like to start by asking you what specific additives would come in under the grandfather clause as those which are usually accepted as safe.

Mr. LARRICK. First, may I thank you for your complimentary remarks.

The grandfather clause as we propose it would essentially separate food additives into three classes. First, those additives which are recognized by scientists generally to be safe. That would include staple foods such as salt, sugar, vinegar, caramel, and many, many others that are common in our food supply.

Second, you have a great many chemicals where the manufacturers, I am glad to say, have done all of the things voluntarily that we would

ask them to do under this bill. They have subjected the chemical to 2 or 2½ years' tests with animals and have come to the Food and Drug Administration, laid these data down before us and we have considered them just as carefully as we know how. We have said to them, we think these are appropriate to use. They are safe. You have shown they are safe. So the grandfather clause would exempt those chemicals where the manufacturer has some formal notice from the Food and Drug Administration insofar as the food supply generally is concerned, or from the meat inspection service, when you are dealing with meats that are under their jurisdiction. In each case industry would have already done the things voluntarily that the law would require them to do.

With respect to those that have not had enough testing and are not generally recognized as safe, all they would get would be a period of time within which they would be required to be tested.

Mr. DINGELL. I wonder if you could give us a list of the first category, the additives which are generally regarded as being safe, such as sugar, salt, vinegar, and additives of that sort. Then we can defend this particular provision.

Mr. LARRICK. If a few examples would be satisfactory, yes. The task of the whole list would be gigantic. I have some examples here of the things that we have shown are not safe. We could very well supply you lists illustrating these three categories.

Mr. DINGELL. Would you mind doing that?

Mr. LARRICK. We would be delighted to do it, sir.

(The information referred to follows:)

A PARTIAL LIST OF CHEMICAL FOOD ADDITIVES GENERALLY RECOGNIZED AS SAFE WHEN USED ACCORDING TO ACCEPTED COOKING PROCEDURES OR AS USED IN GOOD COMMERCIAL PRACTICE

(These chemicals would have to be used so that the food complies with all sections of the Food, Drug, and Cosmetic Act; it is understood that each substance should be of food grade.)

Acacia gum
Acetic acid (dilute)
Agar-Agar
Aluminum and potassium sulfate (alum)
Aluminum sodium sulfate
Amino acids which are normal constituents in foods
Baking powder
Baking soda
Bay leaves
Brandy
Butter
Calcium carbonate
Calcium sulfate
Caramel
Carbon dioxide
Carragheen
Carob bean gum
Citric acid
Cloves
Coffee
Corn oil
Cornstarch
Corn sirup
Cottonseed oil
Cream
Cream of tartar
Dextrin
Dicalcium orthophosphate
Dried skim milk
Ethyl vanillin
Gelatin
Glycerine
Karaya gum
Lard
Lecithin
Lemon extract
Lemon juice
Mace
Magnesium carbonate
Margarine
Methyl and propyl para hydroxy benzoates
Molasses
Monocalcium phosphate
Mono- and di-glycerides of the fat-forming fatty acids (except lauric)
Monosodium glutamate
Mustard
Nitrogen gas
Oat gum

A PARTIAL LIST OF CHEMICAL FOOD ADDITIVES GENERALLY RECOGNIZED AS SAFE WHEN USED ACCORDING TO ACCEPTED COOKING PROCEDURES OR AS USED IN GOOD COMMERCIAL PRACTICE—Continued

Olive oil
Paprika
Pectin
Pepper
Potassium carbonate
Propylene glycol
Salt
Sodium carboxymethyl cellulose
Sodium dihydrogen phosphate
Sodium tartrate
Sorbic acid
Sugar
Tartaric acid
Tricalcium orthophosphate
Vanilla extract
Vanillin
Vinegar
Wine

A PARTIAL LIST OF CHEMICALS THAT HAVE BEEN ACCEPTED FOR USE IN FOODS BY THE FOOD AND DRUG ADMINISTRATION, OR FOR USE IN MEATS BY THE MEAT INSPECTION DIVISION

(Provided their use does not deceive or render the food adulterated or misbranded under sections of the act other than sec. 402 (a) (2).)

Antifoam A: Not more than 10 parts per million
Benzoic acid: 0.1 percent
Benzoate of soda: 0.1 percent
Butylated hydroxyanisole [1]: In meat food products, not over 0.01 percent of the fat content of the meat; in other food, not over 0.02 percent of the fat content of the food
Butylated hydroxytoluene [1]: Not over 0.01 percent of the fat content of the food
Calcium propionate or sodium propionate or any mixture of the two: In bread, not more than 0.32 part for each 100 parts by weight of flour used
Cyclohexylamine: Up to 10 parts per million of the amine (free or combined) in steam that may be in contact with food
Dilauryl thiodipropionate [1]: Not over 0.01 percent of the fat content of the food
Distearyl thiodipropionate [1]: Not over 0.01 percent of the fat content of the food
Monoisopropyl citrate: In margarine—in amount not to exceed 0.02 percent by weight of the finished margarine
Morpholine: Up to 10 parts per million of the amine (free or combined) in steam that may be in contact with food
Nordihydroguaiaretic acid [1]: Not more than 0.01 percent of the fat content of the food
Propyl gallate [1]: Not more than 0.01 percent of the fat content of the food
Resin guaiac [1]: Not over 0.1 percent of the fat content of the food
Saccharin: In some special dietary foods
Sodium or calcium cyclamate: In some special dietary foods
Sodium diacetate: In bread: permitted in not more than 0.32 part for each 100 parts by weight of flour used
Sodium silico aluminate, precipitated hydrated: Satisfactory for use in salt, not more than 2 percent; seasoning, not more than 2 percent; sugar, not more than 1 percent; baking powder, not more than 5 percent
Sulfur dioxide (or sodium sulfite): In molasses, dried fruits, and some other foods—200 to 300 parts per million (not permitted in some foods—see separate list)
Thiodipropionic acid [1]: Not over 0.01 percent of the fat content of the food
Tocopherol: Not more than 0.03 percent of the fat content of the food

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[1] Where two or more of these antioxidants are present in the same food, the total quantity of antioxidant should be limited.

A Partial List of Chemicals That Have Not Been Shown To Be Satisfactory for Uses That Would Leave Residues in Food

(Many of the chemicals appearing on this list are not being used in foods, so far as the Food and Drug Administration knows, but each chemical on the list has been proposed for use in or on food.)

CHEMICAL AND USE

Acetoglycerides: To coat foods and as ingredient of fat spreads
Aceto-olein: Coating on baking pans
Alkyl aryl sulfonates: Cleaning agent
Allyl compounds: Flavoring
Ammonium persulfate: Bleaching agent
Antarox A–400: Wetting agent
Antibiotics (except two antibiotics in uncooked poultry, for which tolerances have been established): Preservative
Benzal acetone: Artificial flavor
Benzo-dihydro-pyrone: Artificial flavor
Beta-naphthoxyacetic acid: Stimulate growth of plants to increase yields
Calcium iodate: Source of iodine in human food (permitted in animal feed)
Carbowax 6000: In a dietary supplement
Cellosolve: Sealing packages—adhesive
Cobalt carbonate: As an additive to salt
Coumarin: Flavoring
Cyclic, glassy phosphates: Sequesterants
DeeO glycose oxidase: Antioxidant
Dehydroacetic acid (except as a pesticide on strawberries, for which a tolerance has been established): Preservative
Dibutyl phthalate: Softener in chewing gums
Diethylene glycol monoethyl ether: Solvent in flavors
Diglycol stearate: Emulsifier
Dimethyl dichlorosuccinate: Preservative
Ethyl gallate: Antioxidant
Ethylene oxide (except as fumigant for spices and copra where tolerances have been established): Fumigant
Ethylene glycol: Antifreeze agent in brine spray refrigeration units
Filtrona Q: Component of plastic that would contact food
GR–I–17: Antioxidant.
Hexamethylene tetramine: Preservative
Hydroquinone: Antioxidant
8-Hydroxyquinoline: Sequesterant
Isopropyl alcohol: Solvent in flavors
Lauryl alcohol: As fatty alcohol in nonstandardized foods
Methyl phthalyl ethyl glycollate: To impart grease resistance to boxboard containers
Nitrated flour (flour treated with nitric acid): Coloring of food
Octadecylamine: Rust inhibitor in steam lines where steam contacts food
Oxo amyl acetates: Food flavorings
Pentachlorophenol: Fungicide
Peracetic acid: Preservative
Phenylacetic acid: Artificial flavors
Polyoxyethylene esters of fatty acids: Emulsifier
Polyoxyethylene sorbitan esters of fatty acids: Emulsifier
Polysorbate 60: Additive to food to increase caloric intake
Polyvinyl alcohol: Thickener
Pyrogallol: Preservative
Quaternary ammonium sanitizing agents: Cleaning agent
Salts of polyacrylic acid: Stabilizer
Soap (sodium oleate): Emulsifier
Sodium 2-chloro-6-phenylphenate: Preservative
Sodium 3-hydroxy-2-naphthoate: Solubilizing agent

Sodium iodate: Source of iodine in human food (permitted in animal feed)
Sodium nitrite on fish fillets and poultry products: Preservative
Sodium silicate: Additive, purpose not known
Sorbitan esters of fatty acids: Emulsifier
Sucrose monostearate: Softener
Sulfur dioxide: Not suitable for use on foods which are good sources of vitamin B_1. (It is permitted with limitation in some foods.)
Triethanolamine stearate: Emulsifier

Mr. DINGELL. To go along with these things that are more or less scientifically accepted by reason of testing and approval by the Food and Drug Administration, would that include long periods of use?

Mr. LARRICK. Yes. We can't stop the food industry short in its tracks. If they have been using, let us say, salt to preserve food for centuries, I would guess that salt has never gone through this modern-day testing technique. Yet everybody recognized that salt not only is safe, but it is necessary. There are literally thousands of substances in that category.

Mr. DINGELL. What would you figure the length of time for this period of continuous use as a means of determining whether the additive is safe?

Mr. LARRICK. I would hate to put a time limit on it. It certainly would be a matter of many years. I would think the extent to which it is used and the likelihood that the type of harm that it might conceivably cause would be observable; I think you would have to take all of those things into account. But bear in mind that the definition of chemical additive for the purpose of this bill is tremendously broad.

Mr. DINGELL. Mr. Commissioner, would you be able to give us some kind of example of something which has been used for a long period of time other than salt? In other words, something which had not been used in the early unrecorded history of mankind.

Mr. LARRICK. I would say vanilla extract.

Mr. DINGELL. You are speaking of natural vanilla extract.

Mr. LARRICK. I think it would be quite safe.

Mr. DINGELL. There were some synthetic vanilla extracts which the manufacturers were compelled to remove from the market.

Mr. LARRICK. That is right. Up to the time that this work was done that was generally regarded as safe. The industry itself ran the tests and they brought the tests to us and on the basis of the tests which they brought forward, we and they agreed that it go off the market. Some other people did not want to take it off the market so we proceeded to take it off the market.

Mr. DINGELL. Assuming this as a statement, would it be fair to say that the synthetic vanilla extract the Food and Drug Administration removed from the market would be a substance that would come under the second portion of the grandfather clause?

Mr. LARRICK. Not now, because we know it is not safe.

Mr. DINGELL. Assuming that you had not removed it from the market?

Mr. LARRICK. Yes. If we had not known what we found out about it. I don't doubt that somewhere in the thousands of items that we use in our food there will be some items that we don't recognize that are capable of causing harm. Still you can't stop all food and say you can't sell any food in this country until it has been tested, because we would be without food for 2½ years.

Mr. DINGELL. I am extremely concerned about this. I want the strongest bill we can get out and at the same time a workable bill. What additives will have to be retested in the 18-month or 2-year period that you propose in the third category?

Mr. LARRICK. Just as an example, there is a firm in the East that is now selling a chemical known as 8-hydroxyquinoline sulfate as a component of a coagulator for cottage cheese. My advisers tell me that in their opinion this chemical has not been sufficiently tested to prove that it is safe. On the other hand, under the present law, we cannot withstand the burden of proof to prove it is harmful. We are somewhat suspicious of it. I would say that chemical would be a first-class illustration of a food additive that would be stopped and that would have to be subjected to that 2½ year testing. Ethylene oxide is used to fumigate certain foods. Ethylene oxide can be used quite safely in some foods like spices that don't have certain protein molecules in them. We know this chemical combines with the protein in certain kinds of foods and we don't know whether the changes brought about in this protein are harmful or not. We don't think ethylene oxide should be used in fumigating that type of food, but it is being used today. There again would be an instance where they would have to come up with evidence of safety or the product would be banned.

We have a case at the moment that is quite interesting. In recent years there has been a tendency to change the whole business of poultry raising. I may say that this bill we are proposing would cover poultry feeds as well as human feeds. Nowadays the poultry feeds are very superior. They have things in them to make the poultry stay healthy and grow fast and so on. One thing they discovered is that if you put fat in the chicken feed it makes them grow faster. Some people were looking for cheap sources of fat. They found a residue from a chemical manufacturing operation that separated fatty acids and glycerine from fat. The residue from this operation was sold to another firm who mixed it with some tallow and shipped it to a lot of feed manufacturers. The upshot of it was that literally millions of chickens were killed in Alabama, Delaware, Georgia, Indiana, Illinois, Kentucky, Maryland, North Carolina, Ohio, and Virginia, and the damage to the poultry flocks ran up in the millions of dollars.

We are presently looking into the question of whether or not this toxic material that killed the chickens goes into the flesh of the edible portion of the bird. This bill would make it a criminal offense to sell an additive like that for human or animal feed until after they had come up with satisfactory proof of its safety.

Mr. DINGELL. This business of the functional value, you mentioned that it is a relaxation of the present law. I am very much concerned about this relaxing of present law.

Mr. LABBICK. In my personal view the requirement that a chemical additive can only be used in a food if it is required in the production or unavoidable is a requirement that impedes progress. I think today in this day and age with 22 million women who are married working that we need convenient foodstuffs. I think the development of convenient foodstuffs make it possible for women to do things

other than slave over a stove is highly desirable. I think if the additive serves a real functional value and adds to the convenience of our food supply, helps produce a more bountiful, more diversified food supply, then it should be permitted in safe amounts even though not absolutely necessary to produce the food.

Mr. DINGELL. Would you give us some instances of that, Mr. Commissioner?

Mr. LARRICK. Just as a simple illustration, if you want to make a ready-prepared cake mix, which millions of women find very convenient in this country today, you need in addition to the ingredients that grandmother used when she baked a cake, ingredients that keep the fat from going rancid, and ingredients that retard hardening of the mix. So almost every one of these convenience foods have things in them that tend to prevent rancidity, that tend to prevent caking, that tend to make the product so that when it gets to the housewife through the normal channels of distribution it will serve the purpose for which she wants it. The working mother can come home from the office and stop at a store and buy some frozen foods and some other convenience items and have a dinner on the table for a whole family in a matter of a very few minutes.

Mr. DINGELL. Would you say, then, that this section would apply to preservatives, antioxidants, and things of that sort?

Mr. LARRICK. Yes, sir.

Mr. DINGELL. Would it apply to other substances? For example, coagulants and anticoagulants and substances of that sort?

Mr. LARRICK. Yes, sir. It would apply across the board.

Mr. DINGELL. What else would it apply to, for example?

Mr. LARRICK. The National Research Council has published a publication that has just recently come out that lists the different types of things that chemical additives do. For instance, in some instances you want to make a food on the acid side for one reason or another, and you call those acidulants. In bottling certain food commodities today, if you want to get the saving that goes with the tremendously fast machine filling of containers you need an antifoaming agent. For example, if you want to put grape juice in a bottle, if you add that grape juice normally with nothing in it, it may you 5 minutes to fill 1 bottle because it will all foam up. You have to wait until the foam comes down. So they have what they call antifoam agents that are present in extremely minute amounts, but those compounds, which have been tested and are wholly safe, will permit that grape juice to go into that bottle with great rapidity. They can speed up the operation and make the saving for the consumer.

Then there are antioxidants. There are things that prevent spattering in cooking fats. There are bleaches. There are buffering agents that keep food from changing to the acid or alkaline side. There are some bulk producers that are desirable. There are clarifying agents used in such things as beer. There are dough conditions. There are various types of curing aids. There are agents that disperse the contents of an emulsion and keep it so your mayonnaise does not separate out into different layers. I could go on and on and on.

Mr. DINGELL. Would you like to give us a list of those?

Mr. LARRICK. I would be delighted.

(The information referred to follows:)

SOME USES FOR WHICH CHEMICAL FOOD ADDITIVES ARE EMPLOYED

Acidifying
Alkalizing
Anticaking
Antidrying (humectants)
Antifoaming
Antihardening
Antispattering
Antisticking
Bleaching
Buffering
Chillproofing
Clarifying
Color retaining
Coloring
Conditioning (dough)
Creaming
Curing
Dispersing
Dissolving
Drying
Emulsifying
Enhancing flavor
Enriching
Firming
Flavoring
Foam producing
Glazing
Leavening
Lining food containers
Maturing agent (flour)
Neutralizing
Peeling
Plasticizing
Preserving (including antioxidants)
Pressure dispensing
Refining
Replacing air in food packages
Sequestering (removing unwanted metallic ions)
Stabilizing
Sterilizing
Supplementing nutrients (yeast food)
Sweetening
Texturizing (improving texture)
Thickening
Waterproofing (wrappers)
Water-retaining
Whipping

Mr. DINGELL. Thank you very much, Mr. Larrick. I would like to repeat the remarks I made earlier about the job I think you have done as Commissioner of the Food and Drug Administration. I think you have done a splendid job. I think you have been one of the very finest public servants in this important field.

Mr. RHODES. Mr. Bush.

Mr. BUSH. Mr. Chairman, I just want to commend the Commissioner for his very fine and clear statement on behalf of this legislation.

Mr. LARRICK. Thank you, Mr. Bush, that is very kind of you, sir.

Mr. BUSH. I listened to it with great interest and the facts as you present them were very clear and very understandable.

Mr. LARRICK. Thank you, sir.

Mr. BUSH. Mr. Chairman, I don't know how long you are going to carry on, but before Mr. Williams left, he gave me some questions he wanted Commissioner Larrick to answer which he would like to have made part of the record.

Mr. RHODES. Mr. Dingell will take the chair and we can continue.

Mr. BUSH. Commissioner Larrick, when you testified before this subcommittee on February 14, 1956, you stated that new legislation dealing with additives to food is needed to fill the gap in the present law which permits untested or inadequately tested chemicals to enter the food supply. Many representatives of the food and chemical industry testifying before this subcommittee in 1956, and again in 1957, also expressed the belief that new legislation in this field is needed in order to further the protection of public health. It is almost exactly 2 years since you stressed to this subcommittee the need for new legislation and in view of the 2 years that have elapsed, I should like to address this question to you: In view of what certainly seems to be a broad area of agreement on this subject between the Food and

Drug Administration and the industries that will be affected by new legislation, don't you think that this current session of Congress should enact a law and thereby provide added protection for the public health?

In other words, I take it that you agree with me that legislation in this field has been a pending matter long enough, and that Congress should now get on with the job and get a law on the statute books. Is that correct?

Mr. LARRICK. I congratulate the chairman on a very splendid statement.

Mr. BUSH. The second one is as follows: Would I also be correct in believing that you and I could agree that it would be a step forward for Congress to enact at this session a law which would provide added protection for the public health, even though the law might not be exactly the bill that I originally had in mind, just as it also might not be exactly the bill that you originally had in mind? In other words, leaving details aside for the moment, am I correct in believing that the enactment of the law providing added protection for the public health would be a forward step?

Mr. LARRICK. Undoubtedly.

Mr. BUSH. No. 3, in view of the need for new legislation, in view of the broad areas of agreement that exist, and in view of the amount of time that has already elapsed without getting a law on the statute books, don't you think it might be a good idea for this subcommittee to try to come up with a bill of its own, if that seems to be the best way of getting a law enacted at the current session? In other words, while all of us know that there are still some issues on which the Food and Drug Administration and the affected industries do not see eye to eye, wouldn't it be a disservice to the public, both on the part of this subcommittee and on the part of the Food and Drug Administration, to permit the current stalemate to continue for another year or longer?

Mr. LARRICK. That would depend entirely, Mr. Bush, in my opinion, upon the nature of the bill that emerged. I think it is our obligation in the Department to acquaint the committee fully with such views as we have from our experience in this field, and to present them forthrightly and vigorously. In the final analysis, it is Congress' job to decide what legislation goes through and whether you adopt our bill or some other bill. We in the Food and Drug Administration will do our best to make it work.

Mr. BUSH. I take it you are very much in favor of the bill that was discussed here this morning, H. R. 6747?

Mr. LARRICK. Very much, sir.

Mr. BUSH. Fifth, let me give you an example of what I had in mind. You have asked for control over the functional value or usefulness of an additive. Industry has expressed almost unanimous opposition to this aspect of your proposal and said that new legislation should deal solely with safety and public health and not with functional values or usefulness. Suppose that, instead of permitting this disagreement to block the legislation altogether, we omitted your proposal about functional value, at least for the time being, with the clear understanding that, if necessary, you can come back next year or the year after and ask us to reconsider the question of func-

tional value if it should develop that our failure to give you control over functional value was in some way interfering with your responsibilities for protecting the public health. I am not saying that the subcommittee will decide to omit from this legislation this matter of functional value, you will understand. I am merely asking whether, if matters do take such a turn, it would not be better for us to enact what we believe to be the best bill we can enact at this time, subject to later review and reconsideration as required? Wouldn't such an approach make sense, from a public-health standpoint, especially since all of us have to face up to the fact that compromise is the essence of the legislative process?

Mr. LARRICK. In my judgment and in the judgment of the Department, functional value is an integral part of the determination of safety and, respectfully, I would recommend against the enactment of the legislation without the functional-value clause. In other words, I would urge that you carefully consider the functional-value problem as a part of the public-health nature of the legislation.

Mr. BUSH. No. 6, as another example of what I have in mind, let us take a look at the means by which the new authority which the legislation will give to the Food and Drug Administration is to be exercised. You have asked for the right to have prior approval, a type of aproach that has sometimes been described as licensing. Others have advocated a delcaratory-judgment approach, while still others have advocated the use of injunctions as more in keeping with the traditional policing role of the Food and Drug Administration in the food field. But all have agreed, I believe, that, whatever the types of approach, the new food additives should not be introduced into interstate commerce until after the Administration or judicial proceedings have been completed. So, whatever the approach, the public health would be safeguarded.

Making the same type of assumption that I made in my question about functional value, namely, thatwe should not permit continuing disagreement to block the legislation altogether, what would you think of a bill giving you most of the added substantive provisions of law you have requested, giving you, also, the authority to enforce these new substantive provisions by means of injunctions, and giving you, finally, the right to come back to this subcommittee for further legislation if the first several years of experience under the new law should indicate that some broader type of enforcement power is needed?

Mr. LARRICK. I would subscribe to the views expressed by Judge Biggs, who spoke for the Judicial Conference. I am not a lawyer, and I don't pressume to have an independent judgment on these things the lawyers seem to love to argue about. But, nevertheless, I must go along with the views of my colleague here, Secretary Richardson, as expressed today. They make sense to me. I am impressed with the fact that we have had a certain review procedure in the pure-food law since 1938. The lawyers that speak to Mr. O'Hara as dissatisfied are the vocal ones. There are a great many of them that tell me they are satisfied with the procedure. Maybe they are just currying favor with me. I don't think there is a universal dissatisfaction with the current review procedures that some of the questions might have suggested.

Mr. BUSH. I might say I am not an attorney, either. However, these are questions that the chairman was very much concerned about in the interest of getting out some kind of a bill that would be helpful not only to you people in the Department, but be a safety measure in benefits to the public health.

Mr. LARRICK. I think this committee has for years made major contributions to the public health in the pure food and drug field, and I have complete confidence that the bill that comes out of this committee will be written with the public interest in mind.

Mr. BUSH. I am sure it will be conscientiously considered.

Thank you, Mr. Chairman.

Mr. DINGELL. Thank you, Mr. Bush. Mr. Larrick, I again want to compliment you, and, with that, the committee will adjourn, to meet at 2 o'clock.

(Thereupon at 12:45 p. m., a recess was taken until 2 p. m., the same day.)

AFTERNOON SESSION

The hearing was resumed at 2:35 p. m., pursuant to the recess.

Mr. LOSER (presiding). The committee will come to order. Mr. Charles M. Fistere will be the next witness, representing the Dairy Industry Committee. Go right ahead, sir.

STATEMENT OF CHARLES M. FISTERE, COUNSEL, DAIRY INDUSTRY COMMITTEE, WASHINGTON, D. C.

Mr. FISTERE. Mr. Chairman, members of the committee, my name is Charles M. Fistere, of 1012 14th Street, NW., Washington, D. C. I am counsel for the Dairy Industry Committee, an organization composed of official representatives of the: American Butter Institute, American Dry Milk Institute, Evaporated Milk Association, International Association of Ice Cream Manufacturers, Milk Industry Foundation, National Cheese Institute, and National Creameries Association.

The Dairy Industry Committee since 1952 has been actively interested in the problem presented by the use of new chemical additives in foods.

In November 1952, the Dairy Industry Committee adopted a short statement of principles which I should like to read to the committee:

1. We believe it is the responsibility of the food industry to exert every effort toward the production and distribution of foods which are wholesome and nutritious and to assure adequate safeguard against contamination or adulteration which would render human food unwholesome.

2. We believe the food industry should continue to improve its food products from the standpoint of nutritive value, wholesomeness and convenience and to increase the economic value of the product to the consumer and in so doing public health should continue to be the paramount consideration.

3. We believe every substance not represented by long usage in human diet should be subject to question as an ingredient in food, and until it has been demonstrated with reasonable certainty by adequate

experimentation that its use in food in the amounts and under the conditions recommended does not present a hazard to public health, it should not be so used, and that appropriate Federal legislation should be adopted to so require.

4. We believe such legislation should require that the results of such experimentation be subject to review and approval by the Federal Food and Drug Administration before the substance is allowed to be used in food sold to the public and should be similar to the provisions found in section 505 of the Federal Food, Drug and Cosmetic Act with respect to new drugs.

Following the adoption of these principles, I was authorized by the committee to collaborate with representatives of other food industries and with the Food and Drug Administration in helping to give effect through legislation to these principles.

Our efforts have proceeded intermittently since that time.

These collaborative efforts plus the hearings which were held by this committee during the 84th Congress and the first session of this Congress, have reduced to a very considerable extent the areas of disagreement on the subject of chemical additives legislation.

My testimony will be addressed to two bills pending before the committee, Chairman Harris' bill, H. R. 6747 and Mr. O'Hara's bill, H. R. 366.

We believe, as the statement of principles set forth, that approval prior to the use of new food additives is necessary. It is the procedure by which such approval is to be determined which is the subject of different judgments.

At the hearings which were held during the 84th Congress the dairy industry was one of several food industries which supported Mr. O'Hara's bill, H. R. 4100, which made provision for resolving the safety question by use of the Declaratory Judgments Act procedure. Mr. Glenn Paxton was the spokesman before this committee on that occasion for several food industries including the dairy industry. We supported the Declaratory Judgments Act approach in the hope and expectation that there would be rather universal agreement favoring it.

It is now clear that is not the case. In view of this, it is our feeling that if the appeals section of H. R. 6747 were amended so as to embody the weight of evidence rule, rather than the substantial evidence rule as now provided for in section 5 of the bill (sec. 409 (h) of the amended act), an adequate review of administrative action would be available.

It would not create a precedent if your committee decided to adopt such a court review provision.

The Commodity Exchanges Act, for example, provides:

> * * * upon the filing of the transcript the court [C. C. A.] shall have jurisdiction to affirm, to set aside, or modify the order of the Secretary of Agriculture and the findings of the Secretary of Agriculture as to the facts, if supported by the weight of evidence shall in like manner be conclusive.

In *General Foods* v. *Brannan* (170 F. 2d 220), the court held that "weight of evidence means the preponderance or greater weight."

In administrative proceedings conducted in accordance with the procedure established in H. R. 6747, the facts for the most part will be derived from opinions of toxicologists, pharmacologists, and other

scientists. There frequently is honest disagreement among these experts in evaluating the significance of test data. That being so, and assuming all scientists to be of equal integrity, why should any final decision rest upon anything but the preponderance of evidence?

Turning to the functional value question, the dairy industry does not favor the inclusion in this legislation of any "functional value" test for several reasons.

In the first place there are at least three powerful provisions in existing law which are aimed at the use of worthless ingredients, that would be ingredients without functional value, in foods. I refer to paragraphs 2, 3, and 4 of section 402 (b) which provide that:

> a food shall deemed to be adulterated (2) if any substance has been substituted wholly or in part therefor * * * (3) if damage or inferiority has been concealed in any manner and (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

These provisions, if invoked, would largely prevent the use of any ingredient which did not perform a legitimate function in food processing, packaging, et cetera.

Moreover, we believe that the question of the functional value of an additive should be determined in the market place. We believe that this legislation should be limited to the matter of safety. If an additive is found to be safe for use under the conditions of its intended use, we feel that if the additive has no functional value, there will be no market for it.

There are two other suggestions which I should like to advance. In connection with the definition of the term "chemical additive," the language at the top of page 2 of H. R. 6747 which includes "any substance the intended use of which may result directly or indirectly in becoming a component, et cetera," it seems to me that this language could bring within the purview of the legislation materials concerning which there would be no reasonable expectation of their becoming components of the food. The definition of a "new food additive" contained in the O'Hara bill is to be preferred over the definition in H. R. 6747.

Moreover, H. R. 366 contains definitions of the term "safe for use" and the term "conditions of its intended use." It seems to me that when the application of a statute to one's business depends upon expert opinion as is the case with this legislation, the more certainty that can be written into the law, the better. I therefore would like to go on record as supporting the proposal made by Mr. George Faunce who testified at the hearings held during the first session on behalf of the American Bakers Association to adopt the definitions contained in Section 2 of H. R. 366.

One further matter, dealing with the application of the amendment. Users and manufacturers of additives should be able to discover whether or not the Secretary regards, a particular material which has been in use as being nevertheless under the terms of the statute a new food additive.

To accomplish this, the witness for the American Bakers Association proposed the addition of paragraph (3) to section 409 (a) under which the Secretary, upon written request, would advise an interested person whether a particular additive was or was not " a new food ad-

ditive." This suggested amendment was contained in exhibit B attached to Mr. Faunce's testimony. I wish to endorse this suggested amendment.

The dairy industry believes that H. R. 6747, if amended in the particulars which I have suggested, would give to the Food and Drug Administration ample tools to cope with the present problem and at the same time afford industry safeguards against possible administrative excesses.

That, Mr. Chairman, concludes the prepared statement and, with your permission, I would like to make one or two additional comments particularly with respect to this matter of a requirement that a new food additive must have, in the judgment of the Government, a functional value. I have been disturbed about this matter from experiences which I have had and it seems to me that the legislation before you is and should be confined to the safety question.

For the reasons I advanced I think this matter of whether material is useful or functional is, on the one hand, going to be determined by the buyers, and on the other hand I say that, if it does not have functional use, there are adequate provisions in the act to take care of those situations.

I judge from colloquy that took place this morning that there may be an impression that this functional value test would be applied without regard to whether or not the material was safe for use or not, and, of course, we must understand and keep in mind that the only materials we are talking about here are those which have a clean bill of health on this safety question.

That being so, I think there are other means of taking care of the question of whether or not the material is useful.

I would despair of anyone trying to devise language which would describe whether or not a material was useful.

It happens in the ice cream industry with which I am familiar. There are additives used which have a very definite useful effect which are pretty unknown to the consumer in that they are useful in producing larger volumes in a shorter space of time and with less spilling over and that sort of thing. The consumer ultimately reaps the benefit of this because thereby the ice cream industry is enabled to put on the market some products that they would not otherwise be able to put on the market.

I seriously doubt that if anybody put his hand to determining what a truly functional use was or a definition of a useful product, they would take into consideration the myriad of things that are useful and perhaps have their primary benefit to the manufacturer but also have a very definite benefit to the consumer.

I think we have a large enough problem here on this question of safety and considering the other safeguards I think it has no place in this legislation.

The other point outside of my prepared statement that I wish to mention was this: I may be mistaken as to the net of the colloquy that took place when the Assistant Secretary was on the stand, but there was discussion comparing the clearly erroneous rule, the substantial evidence rule and the weight or preponderance evidence rule and I took it that the Assistant Secretary was of the opinion that these rules were more or less the same and, if the Government does

feel that way about it, I would strongly urge and would expect no opposition from them to the proposal that we substitute the preponderance of evidence rule for the substantial evidence rule that is contained in the present bill.

Mr. LOSER. Did you say the substantial evidence rule?

Mr. FISTERE. In lieu of the substantial evidence rule.

Mr. DINGELL (presiding). Does that conclude your statement, sir?

Mr. FISTERE. It does.

Mr. DINGELL. Mr. Loser.

Mr. LOSER. I would like to ask one or two questions.

I notice in your prepared statement that you did support a former bill by Mr. O'Hara that had provision for resolving the safety question by use of the Declaratory Judgments Act procedure.

Mr. FISTERE. Yes, sir.

Mr. LOSER. I am not familiar with that bill. Would you just in a few words tell us just what was provided in Mr. O'Hara's bill with reference to the declaratory judgments procedure?

Mr. FISTERE. Well, it was alluded to in the testimony of the witness from the Department this morning.

Mr. LOSER. All I want to know is, On whom was the responsibility placed of filing a petition for a declaration as to safety?

Mr. FISTERE. It could have been done by either party.

Mr. LOSER. Was there no positive provisions with reference to that matter?

Mr. FISTERE. No. The bill, as I recall it, provides that either party would initiate.

Mr. LOSER. No one had the duty placed upon him?

Mr. FISTERE. That is correct, sir.

Mr. LOSER. So that that was nothing. Is that not just about nothing?

Mr. FISTERE. Well, I would say that if the Food and Drug Administration had informally concluded that the material in question was possibly unsafe, they would almost perforce have to go to court and initiate the lawsuit.

Mr. LOSER. The effect of it, it seems to me, without having read the bill, was to place the responsibility upon the Food and Drug Department to have the question resolved if they felt it was unsafe. Certainly the manufacturer was not going to file any declaratory judgments about some of his material. Anyway, that is not before us. And I see that you talk about the weight of evidence rule rather than the substantial evidence rule.

Do you draw a fine-spun distinction between the two?

Mr. FISTERE. I do, sir, for this reason: I have been involved in administrative proceedings before the Food and Drug Administration and I can easily conceive, sir, of a court looking at a comprehensive set of findings of fact which set forth views that had been expressed by various scientists at a hearing and one particular scientist of considerable eminence very likely took one position as against that of other scientists of equal integrity who took a different view of the matter.

Nevertheless you cannot say of this man's testimony that it was not substantial. He has X number of degrees. He has written voluminously on the field. His testimony is substantial and yet, as I have indicated in my statement, the ultimate determination of these ques-

tions involves a good deal of opinion and over against that you could easily have 4 or 5 or 6 or any number of other eminent scientists but the court might say, "Well, that is substantial. It is good enough for us."

Mr. LOSER. You do not insist that the weight of evidence rule is determined by the number of witnesses?

Mr. FISTERE. No, I said eminence and I meant that.

Mr. LOSER. You said 1 on this side and 4 just as eminent or of the same degree of integrity on the other, but numbers will not rule the question of weight.

Mr. FISTERE. Of course not.

Mr. LOSER. And these questions are substantially the same. I think we are playing with words when we talk about preponderance and weight when we review a matter on the record rather than before a tribunal.

Mr. FISTERE. I think, sir, that when you are talking about matters that are really grounded in opinion of science, then I think it is very important.

Mr. O'Hara suggested this morning, I believe, would not a court be inclined to go along with a scientist of the Food and Drug Administration. I am not saying whether they would or not, but conceivably his testimony could be quite substantial and on the other hand other eminent scientists might take quite a different view of the matter.

Mr. LOSER. That can always happen, of course, that scientists may disagree.

Mr. FISTERE. So I come back to my proposition, sir, that if the Department does not regard that there is any important or significant difference between these rules, then for the sake of compromise let them adopt the preponderance of evidence rule.

Mr. LOSER. I do not want to be misunderstood. I did not mean to say that scientists always disagree. What I meant to say was that there are eminent scientists throughout the Nation and in the Department who will come up with different answers to a question and both act with the highest degree of integrity.

Mr. FISTERE. And that is the problem here.

Mr. LOSER. That is a problem and that is the reason that I thought probably the substantial weight rule might be proper.

Thank you so much.

Mr. DINGELL. Mr. Bush.

Mr. BUSH. Mr. Fistere, you represent the Dairy Industrial Committee?

Mr. FISTERE. Yes, sir.

Mr. BUSH. And you list the number of industries here which you represent. Does this committee of which you speak have a memorandum from each of these organizations on this committee?

Mr. FISTERE. If I can take just a moment to explain the setup, the answer is "Yes."

Mr. BUSH. That is all I want.

Mr. FISTERE. Substantial representatives from each of these groups sit on the Dairy Industry Committee; yes, sir.

Mr. BUSH. Then you list the statement of principles which was adopted by this committee. I notice that they were adopted back in November 1952.

Mr. FISTERE. Yes, sir.

Mr. BUSH. Has your committee met since 1952?

Mr. FISTERE. Well, as it happens, sir, as you know these hearings have been on again off again Finnegan since the time that this testimony was prepared which was in February. There has been a meeting of the Dairy Industry Committee and this statement was read to the committee and endorsed at that time.

Mr. BUSH. And they still endorse the statement of principles as you have read them?

Mr. FISTERE. Yes, sir.

Mr. BUSH. I certainly would have no argument with the principles there. I thought perhaps in your experience and in your judgment and in your findings at your various meetings you might have come up with some changes that you might have encountered.

Mr. FISTERE. No; this issue and question has been one which the Dairy Industry Committee has considered very, very frequently in the period since the time of the Delaney hearings and the statement of principle has been reviewed a number of times, as I say, in February, as a matter of fact for the last time and is still endorsed.

Mr. BUSH. I noted that you seem to object to the functional additive.

Mr. FISTERE. Yes.

Mr. BUSH. If some of these functional additives happened to be additives that were not safety functional additives as far as human health is concerned, you would not want to be denied them in that respect?

Mr. FISTERE. I take it that this functional value criterion would have no application at all to a material that was not safe for use in food. It does not come into the picture until it comes in in the determination of whether or not the material is safe. I will give an illustration of why I feel so strongly, sir, about this functional test in legislation of this kind.

In the ice-cream industry we have a problem with the formation of ice crystals when ice cream is placed in a cabinet in a drugstore when the temperature goes up and down and so forth, and you get ice crystals which are unpalatable. Historically there was a material used to overcome that difficulty and it was gelatin. It is used in a minute quantity, at the maximum five-tenths of 1 percent, but since the advent of gelatin for this use as a stabilizer other materials, vegetable gums and the like, have come along that are very much more efficient than gelatin is for this purpose.

Some of them have no nutritive value but when you are talking about a material that is used in a food in the quantity that I am talking about, two-tenths, three-tenths, this nutritive value really has no significance.

Ye, in a hearing to establish definitions and standards of identity for icecream, which hearings were rather long, I represented the International Association of Ice Cream Manufacturers at that hearing and I guess I spent 2 days trying to fend off this proposal which was held by some of the people in the Government that the only suitable stabilizer in ice cream was gelatin when there were much more efficient and, by their own standards, harmless materials used which did a better job.

That is why I am very much concerned about this functional value business in this bill.

Mr. BUSH. That is all, Mr. Chairman.

Mr. DINGELL. Dr. Neal.

Dr. NEAL. I have no questions.

Mr. DINGELL. I was very interested in one thing that you said in response to a question by my colleague, Mr. Loser. You talk about a situation where you might conceivably have one very eminent scientific witness and another very eminent scientific witness or 3 or 4 very eminent witnesses saying on the one hand that the additive is safe and on the other hand that it is not safe in the quantity and way used.

Can you tell me, sir, what your position is in making that statement with regard to the public safety in regard to these additives? Do you not think that the greatest, most important duty of the Congress and Food and Drug Administration in putting together this piece of legislation is preservation of the public safety and not the question of setting up a fine legal procedure or a procedure which will safeguard the rights of manufacturers?

Is not our greatest concern here the concern for the welfare and safety of the people who are going to have to eat these foods with the additives in them?

Mr. FISTERE. Unquestionably, sir, I agree with that statement, of course. The concern and interest of this committee and of the Food and Drug Administration is the public health and safety and I cannot overlook making the point that it is also ours, sir.

Mr. DINGELL. Do you not think that any error that is made ought to be made on the side of safety and that the procedure should so be established that error would be on the side of safety?

Mr. FISTERE. Well, I am trying to avoid or prevent the making of errors. I do not think that errors are going to be made very generally.

Mr. DINGELL. Would it be fair to say that the odds would be much less in favor of error in getting dangerous toxic substances into the foods if we take the more stringent standard of the substantial evidence rule rather than going into the preponderance of the evidence of weight of evidence rule?

Mr. FISTERE. No; I think the public interest would be as well served, sir, by the adoption of the preponderance of evidence rule.

Mr. DINGELL. Do you not think, though, that the substantial weight of evidence rule is a more strict and stringent rule? Is that not your objection to it?

Mr. FISTERE. The substantial evidence rule?

Mr. DINGELL. It is a more strict and stringent rule in favor of the Government and actually in favor of the safety of the people where additives are concerned. Would that be a fair statement?

Mr. FISTERE. Yes.

Mr. DINGELL. For that reason, would it not be better to adhere to that test rather than to some weaker test where we are dealing with substances which conceivably could be extremely toxic and the results of which no one here in the room might even conceive of at this time?

Mr. FISTERE. I think not, because I have seen in my experience administrative determinations upheld on the basis of a modicum of testimony and I think that, where the question comes down to why did the animals die when this work was being done to determine whether the substance was toxic or not, given a panel on two sides of eminent

scientists and considering their qualifications, which is always in the record, a very safe rule would be to adopt the weight of evidence rule.

Mr. DINGELL. Let us get down to this. Let us say that you are going to be one of the citizens who is going to have to eat this food which contains this additive and the animals have died. Which standard do you want to apply to the food which you and your wife and children are going to eat? You are going to want the greatest and most strict standards, are you not?

Mr. FISTERE. I am satisfied that the courts would come out with the right answer if we adopted the preponderance-of-evidence rule.

Mr. DINGELL. You agree with everything I say but not with the ultimate conclusion; is that right?

Mr. FISTERE. I think the courts are going to come out with the right answer but it gives them an opportunity.

Mr. DINGELL. Thank you very much.

Mr. Carrigg?

Mr. CARRIGG. No, thank you.

Mr. DINGELL. Thank you very much.

Mr. FISTERE. Thank you, sir.

Mr. DINGELL. Mr. Chester Adams, a representative of the American Meat Institute.

(Mr. Adams' statement was later received and is as follows:)

STATEMENT OF CHESTER ADAMS, GENERAL ATTORNEY, AMERICAN MEAT INSTITUTE, CHICAGO, ILL.

My name is Chester Adams. I am general attorney for the American Meat Institute, trade association of the meatpacking industry. Our membership consists of about 450 companies of all sizes and located in all parts of the country.

The American Meat Institute has made a careful study of H. R. 6747 and the other food additive bills pending before this committee. On behalf of the meatpacking industry, we have two recommendations to make:

1. We urge the inclusion of the following provision as a substitute for section 9 of H. R. 6747:

"Nothing in this Act shall be construed as an exception to or modification of the provisions of section 902 (b) of the Federal Food, Drug, and Cosmetic Act."

Section 902 (b) of the Federal Food, Drug and Cosmetic Act reads as follows:

"Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act."

For more than 50 years, the Meat Inspection Division of the Department of Agriculture has had the responsibility of conducting a continuous, thorough inspection of all meats and meat food products shipped in interstate commerce. This inspection begins before an animal is slaughtered and continues through every process up until the time the final product is shipped from the plant. Federal meat inspection is recognized as the world's best, and no other food product in this country is subject to the close scrutiny which is given to meat. The superiority and thoroughness of Federal meat inspection were recognized at the time the Federal Food, Drug, and Cosmetic Act was passed, as is evidenced by section 902 (b). The provision exempts meat and meat food products to the extent that the Meat Inspection Act applies, and in section 4 of this act it is provided that products are to be condemned which "contain dyes, chemicals, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food * * *." For more than 50 years, the public interest has been protected by this provision, under which prior approval is required for any additive. There is no reason why the relationship between the Meat Inspection Act and the Food, Drug, and Cosmetic Act should by this legislation be altered or rendered uncertain.

This matter has been considered by the Food and Drug Administration of the Department of Health, Education, and Welfare and the Meat Inspection Division of the Department of Agriculture, and we are informed that both are in accord with this recommendation.

2. Our second recommendation is to delete the reference to the Meat Inspection Act in section 2 of H. R. 6747. The purpose is to eliminate all possible ambiguity. With the reaffirmation of section 902 (b), this provision relating to the Meat Inspection Act would be unnecessary and might possibly lead to uncertainty.

As representatives of the meatpacking industry, we have only these two recommendations to make. However, since some of our member companies do produce food items which are not covered by the Meat Inspection Act, we have had occasion to study the entire question of food-additive legislation, and on behalf of such members we endorse the suggestions made to this committee by Charles Wesley Dunn, general counsel of the Grocery Manufacturers of America, Inc., in a statement presented on July 15, 1957.

Supplementary Statement of American Meat Institute

These additional comments with respect to pending food-additive legislation are submitted for the record with the purpose of clarifying the position of the American Meat Institute and to eliminate the possibility of confusion which may exist as the result of other testimony.

As set forth in our statement, the American Meat Institute has two recommendations with respect to this legislation:

1. We urge the inclusion of the following provision as a substitute for section 9 of H. R. 6747:

"Nothing in this Act shall be construed as an exception to or modification of the provisions of Section 902 (b) of the Federal Food, Drug, and Cosmetic Act."

Section 902 (b) of the Federal Food, Drug, and Cosmetic Act reads as follows:

"Meat and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act."

2. Our second recommendation is to delete the reference to the Meat Inspection Act in section 2 of H. R. 6747. The purpose is to eliminate all possible ambiguity. With the reaffirmation of section 902 (b), this provision relating to the Meat Inspection Act would be unnecessary and might possibly lead to uncertainty.

In our principal statement, we noted that the first of these two recommendations had been considered by the Food and Drug Administration and the Meat Inspection Division of the Department of Agriculture, and we were told informally by representatives of both agencies that they were in accord with this recommendation.

In his statement presented to the subcommittee on April 15, Mr. George P. Larrick, Commissioner of Food and Drugs, made the following comment:

"The witness for the Grocery Manufacturers Association has suggested that the chemical additives amendment should not apply to meat and meat food products because they are regulated by the Federal Meat Inspection Act. The regulation of meat under the Federal Meat Inspection Act occurs in the inspected establishment. The Federal Government under that act does not have jurisdiction over meat that has left the inspected establishment and it has been necessary under the provisions of the Food, Drug, and Cosmetic Act upon occasion to apprehend and remove from the market shipments of meat that is found unfit after leaving the inspected establishment. It would be unwise, we think, to establish a loophole in the chemical additives amendment whereby meat products that are unfit after leaving a federally inspected establishment, because of the addition of poisonous chemicals, would be outside the scope of a Federal law."

To avoid misunderstanding of the amendment we propose, we should like to point out that it does nothing more than reaffirm the present law, and if the Food and Drug Administration has found that it has provided sufficient authority to deal with meat which has become contaminated after leaving a federally inspected establishment, then it should continue to do so. Certainly we agree that the Food and Drug Administration should have the authority to seize product which, after it has been declared fit for human consumption by the Meat Inspection Division, susbequently is rendered unfit. We do not consider that the amendment we propose would limit whatever authority the Food and Drug Administration has. Our point simply is that if the Meat Inspection Act applies to a particular situation, then the Food, Drug, and Cosmetic Act does not. If the Meat Inspection Act does not apply, then the Food, Drug, and Cosmetic Act, as amended, would apply.

Mr. Larrick in his statement commented further:

"The bill (H. R. 6747) would not apply to chemicals that are generally recognized as safe by qualified experts, either on the basis of appropriate scientific studies or prolonged food use. It would not apply to chemical additive uses already shown to be safe to the satisfaction of the Food and Drug Administration or, in the case of uses in meat food products, to the satisfaction of the Meat Inspection Division of the Department of Agriculture. This is the modified 'grandfather clause' of the bill."

Since we have recommended deletion of any reference to the Meat Inspection Act in this "grandfather clause" we should like to comment further on our reasons for doing so and on responsibilities of the Meat Inspection Division. Under the Meat Inspection Act, the Department of Agriculture is charged with the responsibility of examining meat and meat food products to make sure that all such products are "sound, healthful, and wholesome," and contain no dyes, chemicals, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food * * *." (Underlining added.) It should be noted that under this authority the Meat Inspection Division has issued comprehensive regulations governing the use of chemical additives. For example, the use of sodium nitrite, potassium nitrite, sodium nitrate or potassium nitrate, or combinations of these substances, must not result in the presence of more than 200 parts per million of nitrite in the finished product. The use of sulfites, which Mr. Larrick mentions in his statement, is prohibited. In fact, any chemical which is not specifically permitted by the Meat Inspection Division is prohibited, and the Division has for more than 50 years shown an unusually high degree of interest in protecting the public health and welfare. It is not a case of seizing products proved to be adulterated. The Meat Inspection Division for many years has not permitted use in the first instance of additives where it was not satisfied as to their safety. To leave the "grandfather clause" in its present form creates uncertainty because in approving the additives found safe in the past by the Meat Inspection Division, the bill may raise some doubts about the future responsibility of the Department of Agriculture, which of course acts through the Meat Inspection Division. We feel sure that Congress would not wish to impair the authority of the Department, and it is simply to avoid the possibility of creating doubt that we recommend the amendment of section 2 as indicated.

We have one further comment on Mr. Larrick's testimony. After discussing the status of meat and meat food products, he stated:

"The setting of tolerances for chemical residues in meat has already been covered in part in the pesticide chemicals amendment of the Federal Food, Drug, and Cosmetic Act; under that amendment FDA establishes safe tolerances for pesticide residues in meat, just as it would establish safe tolerances for other additives under H. R. 6747.

"We have discussed this procedure with the Department of Agriculture, and it agrees with us that the establishment of tolerances is peculiarly a problem for the Department of Health, Education, and Welfare. This does not mean, however, that there will be a duplication of effort by the two agencies. As we envisage the operation of the statute, and as we have discussed it with the Department of Agriculture, the tolerances would be fixed by FDA after consultation with the Meat Inspection Division of that Department, and Meat Inspection Division would have procedures for detecting unsafe residues in meats, and withholding the stamp of approval from meats with excessive residues. However, if meats with excessive residues should not be detected in the inspected establishment, there would be authority to remove them from the market by seizure in order to protect the public health."

While it is true that the Food and Drug Administration has by regulation fixed tolerances for some pesticide residues in and on meat, it is our belief that the agency has exceeded its authority in doing so. The pesticide chemicals amendment to the Food, Drug, and Cosmetic Act authorized the fixing of tolerances for residues in and on "raw agricultural commodities." Meat is not a raw agricultural commodity, and the Secretary of Agriculture already had full authority under the Meat Inspection Act to condemn meat which it found in its inspection to be unsound, unwholesome, and unfit for human food.

(The following letter with respect to the above statement was received for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D. C., May 20, 1958.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, Interstate and Foreign Commerce Committee, House of Representatives, Washington, D. C.

DEAR MR. WILLIAMS: This replies to your request for comment on a letter dated May 1, 1958, with enclosures, submitted by the American Meat Institute with respect to the Department's chemical food additives bill, H. R. 6747.

The American Meat Institute has recommended two changes that it believes would clarify the intent of the bill and avoid any interpretation which might create a conflict between the Food, Drug, and Cosmetic Act and the Meat Inspection Act.

We anticipated the desirability of determining the precise areas in which the Department of Agriculture and our Department would operate at the time this Department was drafting the bill that is now before you as H. R. 6747, and we met with officials of the Department of Agriculture to be sure there was a clear understanding between us.

The provisions in H. R. 6747 to which the American Meat Institute objects were inserted in the draft bill which later became H. R. 6747, after consultation and in full agreement with the Department of Agriculture. We agreed that tolerances on meat would be fixed by this Department after consultation with the Meat Inspection Division of the Department of Agriculture. Of course, the Department of Agriculture would exercise its present jurisdiction in inspected meat establishments and would determine whether chemicals used in the inspected establishments were being employed properly.

These intradepartmental discussions are reflected in the detailed summary of the principal features of the bill which accompanied Secretary Marion B. Folsom's letter of April 5, 1957, to the Speaker of the House; in that summary, paragraph No. 4, under "Scope of the bill," describes the way the two Departments agree that chemical food additives should be handled under new legislation.

(A further explation appears in the supplemental statement which I submitted on April 15, 1958, when I testified before your subcommittee on H. R. 6747, under "1. Scope of the legislation, (*d*) Status of meat and food derived from animals.")

A study of the material submitted by the American Meat Institute reveals that the institute either does not understand or is not in accord with the program worked out by the two Departments for administering a chemical food additives law with respect to meat. The institute does not believe that tolerances for pesticide residues in meat should be established by our Department. Yet the establishment of these pesticide tolerances by our Department has proved to be a workable procedure that is satisfactory both to the Department of Agriculture and to the Department of Health, Education, and Welfare, and that furnishes adequate public health safeguards. H. R. 6747 would carry forward the same philosophy to the establishment of tolerances for other chemicals.

To make the new legislation perfectly clear and avoid any misunderstanding such as the American Meat Institute now has about the intent of the pesticide chemicals amendment, our Department suggested in its bill (H. R. 6747) the two provisions that the institute would like to have changed. We believe that the recommendations of the Meat Institute, if adopted, would serve not to clarify the intent of the legislation but rather to cause uncertainties. Therefore, we recommend that you do not adopt the amendments suggested by the institute.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

Mr. DINGELL. Mr. Kenyon Loomis, executive secretary of the Adhesives Manufacturers Association of America.

STATEMENT OF KENYON LOOMIS, EXECUTIVE SECRETARY, ADHESIVE MANUFACTURERS ASSOCIATION OF AMERICA, NEW YORK, N. Y.

Mr. DINGELL. Would you give the reporter your full name and the name of the organization you represent?

Mr. LOOMIS. Mr. Chairman, before I begin, may I point out that I have both a written statement that was filed last July and is already filed for the record and my oral statement which is an abbreviated version of the longer statement.

Mr. DINGELL. Do you want your full statement inserted in the record?

Mr. LOOMIS. Yes, I would like to have it inserted.

Mr. DINGELL. Without objection, it will be so inserted.

(The statement referred to follows:)

STATEMENT FILED BY ADHESIVES MANUFACTURERS ASSOCIATION OF AMERICA, NEW YORK, N. Y., ON BEHALF OF THE PACKAGING ADHESIVES INDUSTRY WITH RESPECT TO PROPOSALS TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Mr. Chairman and members of the committee, my name is Kenyon Loomis. I am executive secretary of the Adhesives Manufacturers Association of America, a national trade association representing manufacturers of adhesives for the plastic and paperconverting and packaging industries. The products of this industry are used to fabricate and seal all types of packages and containers which in turn play an indispensable role in the packaging, preservation, and safe shipping of food.

It may help to clarify our position (and a step toward unity of thinking from industry) to tie in our statement with the previous statements of Mr. John C. Kuniholm on behalf of the plastic packaging industry and the statement of Mr. Frederick S. Leinbach speaking for the paper and pulp industry.

We generally concur with the previous testimony of these representatives of the plastic and paper industries in emphasizing that a clearer distinction should be made between food and food packages in considering the amendments to the Federal Food, Drug, and Cosmetic Act. Food packages are not generally supposed to be eaten, but they are important in our modern food distributing system designed to supply the American public with better food in a more sanitary manner. The record shows amazing progress in this respect from the old cracker barrel method to modern sanitary packages. The record also shows there are no known cases where the food package has been injurious to health.

We believe all substances added directly or indirectly to the food for the purpose of effecting the appearance, flavor, texture, storage, or other properties of the food should be classified as ingredients of foods and as foods. We are in complete agreement with the principle that food containers must not render the food packed in them injurious to health. However, we see no reason for including food containers in definitions of food additives whereby the components of food containers would be classified as foods and subject to all the indirect regulations of foods. Such a classification, as the proposed bills generally do, would be improper in our opinion. We believe food containers should be thought of generally not as foods but as essentially inert objects from which only inconsequential trace amounts of substances might incidentally migrate into food without affecting the food or rendering it injurious to health.

Inasmuch as adhesives are necessary components in packaging and paper converting products in food distribution, we are concerned by the definition in a majority of the bills before your committee, which would include packaging materials within the term "food additives," although the former are not deliberate food additives and are not intended to alter any quality or property of food. The packaging component, which may on occasion constitute an incidental or accidental additive in trace amounts, is not intended to become a part of the food, and its presence in food is rare. Under the circumstances, it would ap-

pear that if, after an investigation, FDA finds that the container or package is composed of a substance which may render the food injurious to health, it has adequate powers under section 402 (a) (6).

Section 402 (a) (6) of the present act, in our opinion, covers food containers in an adequate manner to protect the American public. However, our experience indicates a clarification of this section would be helpful and we suggest the following: "If its container is composed, in whole or in part, of any substance which presents a reasonable probability of rendering the contents injurious to health under the conditions of use."

In addition to supporting the distinctions made between food and food packages, we also support the statement of the plastic packaging industry in recommending (1) policing rather than licensing, (2) urging the retaining of the grandfather clause, (3) rejecting the functional value test, and (4) the following specific statements: Inclusion of the term "chemical additive" within the meaning of the term "food" opens a Pandora's box of unimaginable consequences because it subjects packaging components to all of the food laws. Laws written in 1938 with food in mind should not be indiscriminately applied to packaging components without careful deliberation. We believe that appropriate amendment can be made by—

(1) Deleting section 201 (f) (4) and

(2) Rewriting the enforcement mechanism, or adding to section 201 (f) (4) the clause, "Chemical additives shall be deemed to be food for the purposes of sections 402 (a) (1), 402 (a) (2), 301 (a), 301 (c), 302 and 304."

In addition, we suggest clarifying the meaning of the term "safe for use" by adding the following definition to section 201 of the act.

(t) The term "safe for use" when used with reference to a new food additive shall mean that it is reasonably probable that such new food additive can be used under the conditions of its intended use without rendering the food in or on which it is used injurious to health."

In conclusion we wish to make the following point. The adhesives industry is a growing but small industry with annual sales less than $100 million. The industry comprises approximately 60 companies with 90 plants located in every major city throughout the Nation. Most of these companies are properly classified as "small business." Our manufacturing units are small but they perform a necessary service in recommending proper adhesives to keep pace with the technical progress of the packaging industry in developing better, safer, and more attractive packages for food as well as for all industry. We are vitally concerned with the several bills pending before your committee because in their present form they contemplate the imposition of substantial economic and administrative burdens difficult for even our largest corporations, and utterly impossible for the many small-business concerns in the adhesives industry.

Mr. LOOMIS. Mr. Chairman and members of the committee: my name is Kenyon Loomis. I am executive secretary of the Adhesives Manufacturers Association of America, a national trade association representing manufacturers of adhesives for the plastic and paper-converting and packaging industries. The products of this industry are used to fabricate and seal all types of food packages and containers.

The adhesives industry endorses the statements of the plastic and paper industries in emphasizing that a clearer distinction should be made between food and food packages in considering the proposed amendments to the act.

We believe all substances added directly or indirectly to food for the purpose of affecting the appearance, flavor, texture, storage, or other properties of food should be classified as ingredients of foods and as foods.

We are in complete agreement with the principle that food containers must not render the food packed in them injurious to health. However, we see no reason for including food containers in definitions of food additives whereby the components of food containers would be classified as foods and subject to all the indirect regulations of foods. Such a classification, as the proposed bills generally do, would be improper in our opinion.

We believe food containers should be thought of generally not as foods but as essentially inert objects from which only inconsequential trace amounts of substances might incidentally migrate into food without affecting the food or rendering it injurious to health.

Inasmuch as adhesives are necessary components in packaging and paper converting products in food distribution, we are concerned by the definition in a majority of the bills before your committee, which would include packaging materials within the term "food additives," although the former are not deliberate food additives and are not intended to alter any quality or property of food.

The packaging component, which may on occasion constitute an incidental or accidental additive in trade amounts, is not intended to become a part of the food, and its presence in food is rare. Under the circumstances it would appear that if, after an investigation, FDA finds that the container or package is composed of a substance which may render the food injurious to health, it has adequate powers under section 402 (a) (6) of the act.

Section 402 (a) (6) of the present act, in our opinion, covers food containers in an adequate manner to protect the American public. However, our experience indicates a clarification of this section would be helpful and we suggest the following:

If its container is composed, in whole or in part, of any substance which presents a reasonable probability of rendering the contents injurious to health under the conditions of use.

In additon to supporting the distinctions made between food and food packages, we also support the statement of the plastic packaging industry in recommending (1) policing rather than licensing, (2) urging the retaining of the grandfather clause, and (3) rejecting the functional value test.

In conclusion we wish to make the following point: The adhesives industry is a growing but small industry with annual sales less than $100 million. The industry comprises approximately 60 companies with 90 plants located in every major city throughout the Nation. Most of these companies are properly classified as "small business." Our manufacturing units are small but they perform a necessary service in recommending proper adhesives to keep pace with the technical progress of the packaging industry in developing better, safer, and more attractive packages for food as well as for all industry. We are vitally concerned with the several bills pending before your committee because in their present form they contemplate the imposition of substantial economic and administrative burdens difficult for even our largest corporations, and impossible for the many small-business concerns in the adhesive industry.

That concludes my statement.

Mr. DINGELL. Mr. Loser?

Mr. LOSER. I was interested in one statement made by the witness here. He says:

The industry comprises approximately 60 companies with 90 plants located in every major city throughout the Nation.

My city is a major city and I was wondering if you had a plant in Nashville, Tenn.

Mr. LOOMIS. I think you have got me there, sir. We have warehouses but not plants.

Mr. LOSER. Thank you so much.

Mr. DINGELL. Mr. Bush?

Mr. BUSH. I have one question. On page 3, you say:

> If its container is composed, in whole or in part, of any substance which presents a reasonable probability of rendering the contents injurious to health under the conditions of use.

Why do you use the word "reasonable"? Why should you put that word in there? If it is going to render something injurious to health why would you not make it positive?

Mr. LOOMIS. I think we were starting from the other end. The film of glue on the paper or on the package is so thin and supposedly put on with such care that there would be no migration of the chemical from the adhesive into the food, nor would there be any volatile substance coming from the glue into the food at the time of use.

Also, we do feel that under certain circumstances of refrigeration or heat there might be some migration in higher quantities than we consider safe.

Then certainly the FDA would have every right to question the industry on the use of that adhesive.

Mr. BUSH. That is all.

Mr. DINGELL. Mr. Carrigg.

Mr. CARRIGG. Do you have anything at all to do with these containers in which milk is sold?

Mr. LOOMIS. Very much, sir.

Mr. CARRIGG. Is that sort of a paraffin coating on those pasteboard containers?

Mr. LOOMIS. That is part of it. You are talking about the wax protection. We have nothing to do with that, but we do make the adhesive that seals the container.

Mr. CARRIGG. You have to do with this adhesive part?

Mr. LOOMS. Adhesive part, exactly.

Mr. CARRIGG. That is all.

Mr. DINGELL. Dr. Neal.

Dr. NEAL. Thank you. I don't think I have any questions.

Mr. DINGELL. Mr. Loomis, I am very interested in one remark in your oral statement here on page 2 where you discuss the classification of container materials. You say:

> We believe food containers should be thought of generally not as foods but as essentially inert objects from which only inconsequential trace amounts of substances might incidentally migrate into food without affecting the food or rendering it injurious to health.

I presume you are aware of the additives present in foods only in very small and microscopic amounts; am I correct in that?

Mr. LOOMIS. You are talking about deliberate food additives?

Mr. DINGELL. Yes, sir; are very frequently present in food only in the smallest trace amounts. I assume you are aware of that?

Mr. LOOMIS. Yes.

Mr. DINGELL. I assume you are aware also that those trace substances which are added can on occasion and have in the past had very injurious effects on human beings, poultry, and other animals like that. I am sure you are aware of it.

Mr. LOOMIS. You are talking about intentional food additives?

Mr. DINGELL. Intentional chemical additives.

Mr. LOOMIS. You mentioned that this morning.

Mr. DINGELL. You are aware of that fact?

Mr. LOOMIS. I was not aware of it until this morning, of any well-publicized or frequent or persistent instance when a deliberate food additive has been harmful to a large proportion of the human public.

Mr. DINGELL. You were unaware of that fact until you came in here today?

Mr. LOOMIS. We believe that the self-policing of the industry has been of such high caliber and high responsibility that it has been the exception, not the rule.

Mr. DINGELL. Are you referring to your industry, or the food and container industry generally?

Mr. LOOMIS. We are thinking of the adhesive and packaging industry first, of course.

Mr. DINGELL. Of course you understand these bills before us are not aimed at reputable people, but are aimed at the folks who would not come before us and testify.

In view of what you have learned today that additives can be and have been very dangerous, would you be inclined to moderate your views from what you started on the top of page 2 of your oral statement?

Mr. LOOMIS. I think we are talking about two different things. We are making a distinction between a definite food additive and I think in most cases where there has been injury to the health of the public it has been a definite food additive intentionally put in the food.

We are making the point that in those instances when a trace from the adhesive put in the package to put the package together happens to migrate into the food. There are two points. It is going to happen seldom, if ever, and there again the purge of toxic material which might be in the glue which has been diluted by the smooth film of glue would be of such inconsequence that it would not affect the consumer.

Mr. DINGELL. Would you say that if it were found that these inconsequential amounts of food would harm human being, or could conceivably be expected to harm human beings or animals, this committee ought to perhaps take that into consideration?

Mr. LOOMIS. Then I think you are getting down to the subject of tolerances. This morning there were references to a tolerance of 1 in a million, 1 in 10 million.

The adhesive industry itself concerns itself about tolerances, particularly with milk containers, and at one time it was throught that 1 part in 5 million was safe.

The FDA may say it should be zero. Then we come down to the definition of zero. In some cases we have tolerances of 1 in 10 million. If you had a trace amount, we will say, over 1 percent or over a half of 1 percent, that would be something to worry about, but if the traces are 1 in 5 million or 1 in 10 million, then we think it is becoming extreme and going to be burdensome to administer.

Mr. DINGELL. Thank you very much, sir.

Are there any further questions?

Dr. NEAL. Yes.

May I ask just a clarifying question? Do you mind telling us some of the ingredients that go into your adhesives that might in any way

have any potential toward contaminating foods in any way? What are the chemicals? What are the substances?

Mr. LOOMIS. Most of the chemicals that have any toxic quality are not the basic part of the adhesive. They are the preservative part if the adhesive. Most adhesives for packaging are made out of cornstarch or tapioca starch, which are no problem. The new basic raw material is polyvinylacetate, polyvinylalconol.

Now you are getting into the chemical field of adhesive. The FDA has examined these 2 main ingredients and has already set up controls for those 2, but I think where we get into the twilight field is in the question of preservatives and solvents. Formaldehyde is a preservative. They are a very small part, less than 1 percent in many cases, in the glue.

Dr. NEAL. Of course 50 years ago formaldehyde was very prominent and a very acceptable addition to a lot of foods; wasn't it?

Mr. LOOMIS. Yes, sir.

Dr. NEAL. I wonder if it has been your experience or to your knowledge have you ever learned of any deleterious effects at all as a result of the use of formaldehyde in the use of milk other than the taste that it gave it?

Mr. LOOMIS. I don't have enough experience to answer that question. Our feeling on formaldehyde in the adhesive industry is that it is a superior preservative. It preserves the life of the glue longer than substitutes and we have had much conversation and philosophical discussion on this with officials of FDA as to if formaldehyde is going to be eliminated from glue, why not set up a tolerance of the amount of formaldehyde that can go into the milk that makes it safe.

Dr. NEAL. You don't know of any substitutes at all today that might be a source of contamination to foods in packages in which you use those?

Mr. LOOMIS. Not the main raw material of the adhesive. There are certain preservatives which are toxic in themselves but are used under small quantities and under such safe control that we believe that the industry is right in recommending the use of these adhesives, and we personally as far as the industry is concerned, and this is what I was talking about to Mr. Dingell, have had no proof or no reaction can go back that the use of these glues has hurt anyone.

Mr. NEAL. You have had no difficulty in convincing FDA that the quantities or the limitations with which you use these things are in any way destructive to health?

Mr. LOOMIS. Yes, we have had conversation and correspondence with FDA, not the association, but industry manufacturers.

Dr. NEAL. Have they restricted the use of those things that you are using at the present time? Have they eliminated any of the drugs?

Mr. LOOMIS. Yes, they eliminated. We have had retained Syracuse University along with some large packaging manufacturers to examine and test these different glues for us and in cooperation with Syracuse and in correspondence with FDA. There have been certain preservatives restricted by FDA in use on milk containers.

Dr. NEAL. So far that action on the part of the Food and Drug has not been sufficient to interfere to any great extent with the industry?

Mr. LOOMIS. Its actual action has not interfered. We get a little disturbed by the basic philosophy. We are a little disturbed by their concept of zero. We think if the migration is 1 part in 10 million,

that is practically zero, but they will come back to the per se doctrine and say it is there and has to come out.

Not the entire industry, but in general we accept the fact that a milk carton is a little different than a carton of cocoa. Milk is being drunk every day in great quantities and being used by the young people, and because it is a very daily food FDA has to be much more careful and we accept that, but we also feel that tolerances are sensible and would be administrative self-policed by the industry. The thing that concerns us is that if we have to submit all samples, and all formulas, and all tolerances to Washington the burden of the administration of that program would cost this industry a lot of money and would be very burdensome to FDA.

Dr. NEAL. Then just one other question. Have you found at any time in your complaints or in your hearings before the Food and Drug Administration that there has been any disposition at all to be unreasonable in their requirements?

Mr. LOOMIS. I have not personally appeared before Food and Drug and I have not personally engaged in these discussions officially with Food and Drug, but I would say in general the Food and Drug Administration has been very reasonable.

Dr. NEAL. In other words, your industry is not particularly dissatisfied with things as they go naturally?

Mr. LOOMIS. Not a bit; no.

Dr. NEAL. Thank you.

Mr. DINGELL. Mr. O'Hara?

Mr. O'HARA. No questions.

Mr. DINGELL. I thank you very much, sir, for your appearance and for your very courteous statement. Is Mr. Chester Adams in the room?

If there be no objection then by the members of the subcommittee Mr. Adams may have until the regular time to file his statement.

Is the representative of the National Health Federation present in the room? May I ask at this time whether there is any one present who has a desire to be heard who has not been heard so far?

Mr. O'HARA. Did Mr. Fistere testify?

Mr. DINGELL. He has already testified.

Mr. O'HARA. He indicated to me that he would have to be away tomorrow and would have to testify today.

Mr. DINGELL. He has testified and in fact we have heard all witnesses who were to be heard today with the exception of the gentleman seated there now, the representative of the National Health Federation.

Would you give your full name and address to the reporter?

STATEMENT OF WILLARD GLEESON, VICE PRESIDENT OF THE NATIONAL HEALTH FEDERATION

Mr. GLEESON. My name is Willard Gleeson, vice president of the National Health Federation. The National Health Federation I guess is in a peculiar position in that it speaks for the people, the consumers of the products that are affected by these additives.

Mr. LOSER. I didn't understand. You say you are in a peculiar position speaking for the people.

Mr. GLEESON. That we speak for the people that consume these additives. We have no manufacturing. We are not interested in the manufacturing angle of these additives whatsoever. I think I can make our position very clear by just this kind of a statement.

Mr. GLEESON. We feel that industry in this age of high-speed production and high-speed transportation can adapt itself to the needs organically of the consumer by inventing, as it were, those things that are beneficial in the food for the benefit of the human body, whereas the human body cannot adapt itself to poisons even in very small amounts, and we urge this committee to take that into consideration.

A watered-down bill that would have grandfather clauses in it that would leave in use even in very small proportions poison additives that would accumulate in the human system could result in disaster to many of our American citizens.

We, therefore, urge that the committee give very careful consideration to the Delaney bill, H. R. 7798.

We feel in that bill the public gets its best protection.

I think that, Mr. Chairman, states our position.

We submitted a letter and two enclosures that we would like to have printed in the record.

Mr. DINGELL. May I ask how long they are, sir?

Mr. GLEESON. The letter is only a little more than a half page and the enclosures are 4 pages.

Mr. DINGELL. Is there any objection to the inclusion of the letter? It will be so included.

(The letter is as follows:)

NATIONAL HEALTH FEDERATION,
San Francisco, Calif., April 10, 1958.

INTERSTATE AND FOREIGN COMMERCE COMMITTEE, HOUSE OF REPRESENTATIVES,
House Office Building, Washington, D. C.

GENTLEMEN: Our organization hereby goes on record for its members and affiliated organizations and their members, in support of the Delaney bill, H. R. 7798, and request your committee to report said bill out without amendment.

Please make this request a part of the record in the hearings of April 15 and 16, 1958, together with the attached document by the nationally famous expert in the additive field, Dr. Duon Miller.

This document of Dr. Miller's clearly sets out for you the effects of the additives now in use on the children and people of our Nation and the results to us, if we fail to stop these additives now.

Only the Delaney bill, H. R. 7798, eliminates the poison additives now in use.

As a Nation, for our safety we cannot permit any toxic material to be used in our food or our drinking water (fluorides).

Gentlemen of the Congress, please remember your body cannot adopt itself to poisons and toxic additives the makers put in food and water, but the makers of these foods can adapt their products to organically pure foods without these poisonous dangers. So make the producers do the adapting for the protection of you and your Nation and its people.

Need we say more to secure your favorable action?

Yours truly,

W. L. GLEESON,
Vice President.

CORAL GABLES, FLA., *February 5, 1958.*

AN OPEN LETTER TO OUR BOARD OF EDUCATION

Congratulations on an apparent (I hope, sincere) move by your group to better the education of our children in the public schools.

Lowell Thomas recently, in a radio address, detailed how foreign countries, even Russia, Germany, etc., have far superior teaching programs for their children, and how much further advanced those children are than the children in our country.

The problem of smoking areas in school is interesting. Although I am against it, I think there are matters far more important than that, and many of the hours spent on some subjects are of insignificant benefit to a child in later years.

After extensive research, I'm sure nothing more important could be taught in our public schools than basic nutrition.

Dr. D. T. Quigley, M. D. of the University of Nebraska, has just quoted an eastern college survey as follows: "999 out of every 1,000 people, lack the proper nutrition—only 2 persons out of 2,511, are receiving the vitamins, minerals, and proteins they need."

Look at the average child in our schools today. It shows on his face he is suffering from malnutrition. He has a pointed face, he is emaciated, he's not robust, and if he had to mow the lawn for a couple hours, he would be physically exhausted.

In a recent study, photographs (rear photographs of their bodies) taken of both boys and girls, revealed that it is amazingly difficult to tell which is a boy and which is a girl. The boys of today have more feminine characteristics than they did years ago and the girls are more mannish. This is due to malnutrition, and has been documented.

One leading university made an extensive study of nutrition and alcoholism. Rats and other animals were used, and in each enclosure was a dish of alcohol and a dish of water. As long as the animals received their proper diet, they would drink the water and leave the alcohol alone. If the diet was tampered with, they would refuse the water and drink the alcohol. When the diet was restored to normal, they would leave the alcohol and go back to the water.

This is easily applied to humans. If you will ever visit the court and see the drunks brought before the judge, you will not find one drunk who is not suffering from malnutrition. Recently a member of the FBI told me that they made the interesting observations on criminals suffering from malnutrition.

In our own schools where you find delinquency, you will find those same individuals suffering from malnutrition. You will never find a child who is fed right and lives right, ever becoming a juvenile delinquent. Our juvenile courts will verify that.

Nutrition, as directly related to juvenile delinquency was discussed recently at a meeting of the Advertising Club in Washington, D. C.

It was brought out that the processed foods found on the average table of today are responsible, to a great degree, for the horrifying situations in which so many teen-agers are finding themselves. Also the crimes committed without passion or jealousy by juvenile delinquents—killing for the sheer thrill of killing—must be conceived and committed by sick, demented minds—victims of malnutrition.

It was also pronounced as shocking that the most overfed Nation (United States) in the world is rapidly becoming the most undernourished. This can lead only to utter disaster, especially since most of the public innocently believe that our pure food laws protect us from eating anything harmful to our health. Nothing could be farther from the truth. It is reported that 99 percent of our population is eating over 276 untested, unquestionably dangerous, poisonous chemicals.

The University of Southern California, in reporting on mental illness, outline malnutrition as causing: mental confusion, ideas of persecution, loss of memory, disorderly thinking, irritation, mania, hallucinations, and dementia. Doesn't this open your thinking on juvenile delinquency?

Calcium, the most important mineral in our body, is extremely deficient in the American diet. Calcium controls the I. Q. of every individual. Show me a child who is a "cola fiend" and I'll show you a poor report card. Stop the colas and watch the report card improve. If a child were taught basic nutrition, he would know that fluoridation (rat poison) in the drinking water, obstructs the absorption of calcium by the body, retards mental thinking pathetically.

When our children learn to shun "colas" as they would a rattlesnake and learn to live and eat as our Creator intended—polio, cancer, heart trouble, rickets, pellagra, etc., etc., will be eradicated.

Is it any wonder a careful 10-year check reveals that 75 percent of our children are sickly because of malnutrition? No wonder what Selective Service records show 52 percent rejections, with a high percentage rejected because of extremely low mentality.

What about the girls—the mothers of tomorrow? So few are properly equipped, both physically and mentally, to become true mothers. They themselves cannot be blamed—their parents and our educational system are solely to blame.

For example, Miss X gets married, she knows nothing about building up her body for the coming of a possible future blessed-event. She knows nothing of her health, her diet, and the requirements of her unborn child. Is it any wonder motherhood is justly feared and we have so many sickly, unhealthy babies? It's pathetic—whereas if she had been properly taught, she would not fear motherhood and would produce a healthy, intelligent, happy baby. Livestock owners know and practice scientific principles our American girls know nothing about.

It is up to our schools to educate our children in correct nutrition and health. The average parent is ignorant and incompetent on this subject. Our daughters cannot depend upon the "O.B.", as his scientific knowledge on motherhood is invariably "nil". Chances are, his only advice will be "cut down on your eating if you want a small baby". This theory has long been disproven, (but he knows nothing else to say) unless he tells her, to prevent morning sickness during pregnancy, drink several cokes a day. Right here in Miami is a horrifying example of this—a baby was born (to a coke mother) without any fingers or toes—in Texas a boy was born without legs or arms. You can't produce healthy children by drinking calcium-destroying soft drinks, loaded with phosphoric acid and white sugar.

After the baby is born the "O.B." suggests a pediatrician take charge and I have yet to meet one as well qualified as my bootblack or one who knows the first basic principle of child nutrition. Their main program consists of criminal shots for everything imaginable—none of which are of value, except to violate God and Nature's laws and completely upset the baby's health for his entire life.

According to American Dental Association, 50 percent of the babies have at least one cavity before the age of 2. Do you remember anything like that in your childhood?

Can't you see now that it is most important that our schools must at least teach basic nutrition—it certainly is. Schools in many cities are now teaching it and the students find it very interesting—they become health minded—read health articles—become healthier individuals and in future years, we won't be filling up hospitals as fast as they are built and have new medical clinics going up on every corner.

One thing certain—this is not a controversial matter—you will find every thinking parent 100 percent in favor of this humane program for the good of our Nation and especially our children.

Respectfully yours,

DUON H. MILLER.

AN OPEN LETTER TO DR. LEROY E. BURNEY

CORAL GABLES, FLA., *January 8, 1958.*

Dr. LEROY E. BURNEY,
United States Public Health Service,
Washington, D. C.

When you report to the Associated Press—"the incidence of all types of polio declined 62 percent in 1957 as compared with 1956, and paralytic cases declined about 73 percent"—upon what facts do you base such a ridiculous statement?

If these figures are a brain child of the National Foundation for Infantile Paralysis, that alone will label them worthless as far as being truthful is concerned. Knowing the inner workings of this corrupt group from their president down to their local "hatchetmen," I trust giving out these false percentages was not intentional on your part. Why continue taking the public on an expedition into Alice of Wonderland?

First, their president, Basil O'Connor, know of clinics in this country who have long successfully treated polio, has received invitations to visit the clinics and even when he is in their vicinity he ignores them—why? Does he place gold before God?

Second, an M. D. lecturing for them at a public meeting admitted they had no immediate positive diagnosis for polio—so for the past several years it is very clear that they "juggle" the figures erroneously, simply to brainwash and lie to the public. We expect the truth from public servants.

If a sick child were brought into your office, could you, any member of your Department, or any member of AMA that you know give an immediate, correct and positive diagnosis as to polio. I doubt it.

You'll recall the puppets in the old fashioned sideshow where they danced, sang, etc., yet didn't have a brain in their head but were simply doing the planned wishes of the "experts" pulling the strings. It looks like the money beggars and the monkey-juice peddlers are pulling the strings with our health (?) officials, dancing and singing while innocent little children die from the unnatural injection of a foreign protein into the body in violation of every law of God and nature.

Polio is a condition—as is a sprained ankle. It is not a disease caused by any mysterious live virus, as no such virus exists. Polio vaccine has never prevented, or mitigated polio in even 1 child or adult—yet look at the deaths on the doorsteps of vaccine.

An honest congressional investigation would shock this Nation. I suggest you call for such an investigation immediately. Let us bring order out of chaos, eliminate this shameful "racket," prevent further suffering, deaths, and disgrace. You may rest assured I'm eager and willing to cooperate without any personal recompense.

Will greatly appreciate a copy of the department's findings of fact which you no doubt have had prepared to support the press release referred to in the first paragraph of my letter.

Respectfully,

DUON H. MILLER.

Mr. DINGELL. Mr. Loser.

Mr. LOSER. I was just interested here in the first paragraph of your statement about a magazine known as the Herald of Health and Naturopath.

Mr. GLEESON. That is Herald of Health. It is not Naturopath. It used to be the Naturopath, and our organization took it over. It is an oldtime publication.

Mr. LOSER. It has no connection with naturopathy?

Mr. GLEESON. No; none whatever.

Mr. LOSER. Does your federation publish material that is favorable to unorthodox methods of treating serious diseases, such as the Hoxsey treatment for cancer?

Mr. GLEESON. Mr. Congressman, we try to publicize both sides. Broadcasting is my business and, in 30 years as a pioneer broadcaster, I have learned that the American people, if you give them both sides of the issue, usually come up with the right answers.

Mr. LOSER. I believe you did denounce the use of Salk vaccine.

Mr. GLEESON. We didn't denounce it. We suggested that the people take a little more care in determining its value and its effects on the children of this country.

Mr. LOSER. That is all.

Mr. DINGELL. Mr. Bush?

Mr. BUSH. I have no questions.

Mr. DINGELL. Mr. O'Hara?

Mr. O'HARA. No questions.

Mr. DINGELL. Dr. Neal?

Dr. NEAL. You represent the national federation; is that right?

Mr. GLEESON. Yes, sir.

Dr. NEAL. Looking at the second paragraph of your statement here, I am rather amazed at this statement:

> The National Health Federation is exceedingly critical of the medical profession, the drug-manufacturing industry, the Food and Drug Administration, the United States Public Health Service, the American Cancer Society, and the American Medical Association.

Is that your statement?

Mr. GLEESON. No, sir.

Dr. NEAL. The statement is headed "The National Health Federation."

Mr. LOSER. If the gentleman will yield, that is not his statement.

Dr. NEAL. You are opposed to the American Medical Association and the American Cancer Society?

Mr. GLEESON. We are not opposed to anything, Mr. Congressman. We are only interested that those organizations give the people a complete story of both sides of the issue, so that the public can decide.

Dr. NEAL. You don't deny the progress that has been made in medicine all these years, do you?

Mr. GLEESON. No, sir. Being a broadcaster, I am interested in progress, obviously.

Dr. NEAL. You fully recognize that medicine and sanitation and immunology and prophylaxis and all that sort of thing has done more for this country than it has ever done for any people in the world?

Mr. GLEESON. There is no question about that.

Dr. NEAL. Then you do not object to, and you do not criticize, the general health measures that have prevailed here in the United States?

Mr. GLEESON. If they will reveal to the American people, sir, both sides of the issue, what might be dangerous, what might be held back from the people. We are utterly opposed to censorship in any form to the American people.

Dr. NEAL. Do you feel that any of these institutions, the American Medical Association or the Food and Drug Administration or any of these other institutions that I mentioned a while ago, have done something to interfere with the progress of general medicine and health in this country?

Mr. GLEESON. We have found some cases; yes. We have some records in our office to that effect.

Dr. NEAL. Occasional records?

Mr. GLEESON. Yes, sir.

Dr. NEAL. Did you find that in any institution that involves 150 million people?

Mr. GLEESON. You will find that among broadcasters, sir.

Dr. NEAL. All right. Thank you.

Mr. DINGELL. Is there anyone else present today who desires to be heard on this matter?

Would you give your name, sir?

Mr. DUNN. Mr. Chairman, I spoke with Chairman Williams this morning, and asked the privilege of making a brief supplemental statement to the one I made last July.

Mr. DINGELL. Yes; I understand that you were to be heard tomorrow.

Mr. DUNN. That would be quite satisfactory.

Mr. DINGELL. Mr. Painter, did I understand that Mr. Delaney was on his way down?

Mr. PAINTER. Yes.

Mr. DINGELL. Mr. Dunn, would you mind waiting then? We will put you on the stand right after Representative Delaney.

Mr. DUNN. Of course not.

Mr. DINGELL. I notice Mrs. Loser in the audience. It is not only an honor to have you with us, Mrs. Loser, but it is an honor to have your guests. I know I speak for every member of this committee when I say I have the greatest fondness for your very distinguished and very able husband and it has been a real pleasure and a real honor for me to sit next to him on this committee for now about a year and a half.

Mr. LOSER. Thank you so much.

Mr. O'HARA. Mr. Chairman, I wonder if the record has been cleared up a little bit with reference to H. R. 366.

Mr. DINGELL. Mr. O'Hara, I would like to say that after you left the room I went into the matter again with the Under Secretary of Health, Education, and Welfare on the precise point that you discussed and, as near as I understand, the record has been corrected, but I can assure you that the record will be further corrected.

Mr. O'HARA. I hope so, Mr. Chairman. I had not seen a copy of the bill for a year and a half and I had it reminded to me that somebody had drawn the wrong conclusion this morning.

Mr. DINGELL. We will insert in the record at this point a statement by Mrs. R. I. C. Prout, president of the General Federation of Women's Clubs, and a statement of the Society of the Plastics Industry, Inc., which was forwarded to the committee. Both of those will be included in the record at this point.

(The documents are as follows:)

STATEMENT OF MRS. R. I. C. PROUT, PRESIDENT, GENERAL FEDERATION OF WOMEN'S CLUBS

The General Federation of Women's Clubs has always been interested in the Pure Food and Drug Act and believes the strict enforcement of such a law is vital to the health of our people.

We also believe that to be effective, and any definition must clearly state its purpose, and that this amendment for use of additives for the preservation of food should be so specific that no such additive can be used which could possibly deceive the public in its interpretation.

We also believe that no additive should be permitted until such substance has not been thoroughly tested so as to be certain that its use over a period of time, or in quantity, will not be injurious to the health of the consuming public.

We urge your committee to present in your definition a standard that gives to the consumer public every possible protection.

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.,
New York, N. Y., April 15, 1958.

Hon. J. B. WILLIAMS,
Chairman, Health and Science Subcommittee of House Interstate and Foreign Commerce Committee, United States Congress, Washington, D. C.

DEAR CHAIRMAN WILLIAMS: The purpose of this letter is to advise the Subcommittee on Health and Science of the Society of the Plastics Industry, Inc.'s support for H. R. 10404 (introduced by you on January 30, 1958).

On July 17, 1957, the society, represented by John G. Kuniholm, chairman of the Society's Food Packaging Materials Committee, and Jerome H. Heckman, counsel to the society, appeared before your committee prepared to testify concerning the proposed "food additives" legislation now pending in the Congress. Although scheduled to appear according to the committee's witness list, the unexpectedly lengthy testimony of other witnesses made it impossible for us to take the stand on July 17. However, our statement supporting H. R. 8390 (the second Harris bill) was submitted to your committee and accepted for the record. A copy of our earlier statement is attached to this letter for your convenience.

We are well aware of the tremendous amount of important business now on the House Interstate and Foreign Commerce Committee calendar for this session of Congress. Likewise, we are aware of the general desire to conclude the "food additives" hearings promptly so that a worthwhile bill can be reported out. In view of these two important considerations, we are willing to forego oral presentation of our position, but we respectfully urge the subcommittee to consider our July 17 statement, as amplified by this letter, very carefully.

In so doing, the subcommittee will find that in July we strongly supported favorable consideration for H. R. 8390, with some modifications. This was in keeping with our approval of a "notification" type measure for control of food adidtives used as packaging components, as contrasted with an unnecessarily burdensome type of "licensing" procedure.

The society's position in this matter was first approved by its board of directors on June 28, 1957 when the following resolution was adopted:

"*Resolved* The Board of Directors of the Society of the Plastics Industry, Inc., endorses and approves the philosophy of 'notification' in food additives legislation. By notification is meant the establishment of procedures whereby the proponent of a new food packaging material may ship it for use without the prior approval of the Food and Drug Administration upon the expiration of a suitable period after the submission of data showing that such material is safe for use under the conditions of use;"

At least insofar as the plastics packaging industry is concerned, the hearings which have taken place before your subcommittee since that time have served to point up the soundness of the approach enunciated in this resolution. Congressman A. L. Miller who appeared on July 18, as well as the eminent scientists who appeared as a part of the excellent panel discussion before the subcommittee on August 6 and 7, gave particularly convincing testimony to the fact that new packaging components are already being adequately pretested by industry, and that a sensible notification procedure would be entirely adequate to afford the public any needed additional protection by formalizing the presently self-imposed requirement for laboratory pretesting.

On the other hand, the hearings have also shown that the only added purpose which some of the other bills before you—especially the Food and Drug Administration sponsored bill (H. R. 6747)—would accomplish would be an unnecessary hamstringing of industry development, the throttling of smaller businesses (of which there are so many in the plastics industry), and the overburdening of the administrating agency unless there were a tremendous increase in its budget.

With full recognition of the testimony heretofore given you, and after a further appraisal of the overall additives situation as it may involve plastic packaging components, the society's board of directors passed a new resolution just last month reaffirming its earlier view.

In accordance with this latest resolution, it had been planned to inform your subcommittee once again of the society's support for H. R. 8390, with the two modifications suggested on page 6 of our earlier statement. However, just last week, we learned of a new bill which you have introduced, H. R. 10404, and we have now had an opportunity to review this measure. Having done so, we wish to give our endorsement to this proposal since we find that it embodies the best features of H. R. 8390, H. R. 6747, and the other pending bills. Also, we note with approval that H. R. 10404 is the first measure introduced which would properly protect industry from unnecessary and unfair disclosure of unique trade processes or methods.

It is our sincere belief that the adoption of H. R. 10404 will accomplish the salutory ends envisaged by such measures as H. R. 6747, thereby affording the public full protection without unreasonably overburdening the already flounder-

ing small-business economy. Equally as important, the adoption of H. R. 10404 will obviate the necessity for an enormous increase in the Food and Drug Administration budget at a time when much congressional energy is, and should be, directed toward reducing nondefense spending.

As noted previously, this restatement of the society's basic position and indication of our support for H. R. 10404 is being submitted in lieu of oral testimony. At the same time, however, we wish to advise the subcommittee that we stand ready to appear before you if there is any way in which we can be of further assistance in these important matters. Meanwhile, we respectfully request that this letter be included in the record, and we urge favorable consideration of H. R. 10404.

Very truly yours,

JOHN G. KUNIHOLM,
Chairman, Food Packaging Materials Committee, Society of the Plastics Industry, Inc.

(NOTE.—The statement referred to in the above letter appears on p. 149.)

Mr. DINGELL. We are honored to have with us today our very distinguished friend and colleague, an able and sincere Member of this House of Representatives, Mr. James Delaney, Representative from the State of New York.

On behalf of the members of the subcommittee I would like to extend to your our warm welcome and our appreciation for your having come down to discuss the food additives bill of which you are a sponsor and to recognize you for whatever statement you would like to make.

STATEMENT OF HON. JAMES J. DELANEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. DELANEY. Thank you, Mr. Chairman. It was my understanding that I was to testify in the morning and I possibly could have gotten here earlier had I known that you were going to close hearings today or attempt to close them.

However, I have a brief statement that I should like to make part of the record.

Mr. Chairman, and members of the committee, it was a little over a year ago that I was heard in support of my additive bill. Since that time, you have listened to a great deal of testimony, much of it conflicting, and I appreciate this opportunity to recapitulate and reemphasize some of my views on chemical additive legislation.

May I say that I also appreciate the amount of time and the seriousness consideration you have been giving the additive bills. I am sure that by now you can have no doubt as to the necessity of protective legislation in this field.

However, the question remains—What form should the legislation take?

My bill, H. R. 7798, has but one purpose—to give the public the fullest measure of protection possible. I know that various of its provisions do not please the industries involved, but I am much more concerned with the public health than I am in accommodating the convenience of the industries.

I believe that H. R. 7798, together with Mrs. Sullivan's H. R. 7938, offers greater protection than the other bills before you, and I should like to comment briefly on certain salient points. Hereafter, when I speak of H. R. 7798, I also include H. R. 7938.)

As I have previously stated, the bill contains no grandfather's clause. Industry representatives at these hearings have frankly admitted that they want such a clause, but I feel strongly that no exemptions should be granted.

As you know, the Food and Drug Administration has estimated that there are at least 150 chemical additives now in use that area in a sort of scientific no man's land. That is, their safety has not been proven beyond a doubt.

If all or any of these chemicals are not brought within the scope of any legislation enacted, the very reason for the legislation will be bypassed. What sense would there be in your protecting me against new poisons if I am forced to keep on ingesting old poisons?

The FDA bill, H. R. 6747, has a provision which seems to have some grandfather possibilities. It would exempt an additive if it has been shown to be safe through "prolonged use" in food. However, it does not define "prolonged use."

Just how long is "prolonged use"? Two years? Five years? Ten years? And if adequate tests have not been made, how can a criterion be established for safety through "prolonged use"? In the case of some chemicals, it might take as long as 20 years for their accumulative effect to be felt.

Other bills (H. R. 8390 and H. R. 366) do not specifically give exemptions, but they deal only with "new food additives," thus conveniently ignoring those now in use. H. R. 10404 exempts chemicals in use before January 1, 1958.

Mr. CHAIRMAN. I do not wish to appear unduly critical of the other bills, but I do want to have my opposition to a grandfather's clause thoroughly understood.

There is a provision in my bill which is not contained in the others, and I feel that it is an important one. That is, a chemical additive must serve a purpose which will be useful to the consuming public.

This provision is extremely unpopular with the industries. They have even quarreled with the rather wague requirement in the administration bill relating to an additive's functional value, although it does not state whether the additive should be of functional value to the consumer or to the industry.

Considering the present practices of many of the food industries, a usefulness-to-consumer requirement is needed to insure the nutritional standards of our foods.

For instance, chemical emulsifiers and synthetic egg colorings, which have no nutritive value, are widely used in place of natural food ingredients, especially in baked goods. Baking soda has been added to sour milk to make it appear sweet when used in the making of ice cream. Synthetic sweeteners are used to replace sugar. These are but a few illustrations.

The substitution of inexpensive chemicals for valuable natural substances cannot be justified on any grounds. The nutritional standard of our food supply must be jealously guarded, and a usefulness-to-consumer provision is essential.

H. R. 7798 is the only additive bill which contains a specific provision prohibiting the introduction of any carcinogen into food. My testimony of March 29, 1957, gives the reason why I felt impelled to include such a provision.

I am aware of the fact that conflicting scientific opinions have been expressed here regarding this provision.

In this field, I am a layman, and I do not claim to have any special knowledge of medicine. However, when the public health is involved, and the experts disagree, then, as a legislator, I feel I must support the experts whose opinions appear to most strongly safeguard the public health.

The carcinogen prohibition in my bill follows the recommendations made by the International Union Against Cancer in Rome, in August 1956. It is supported by the three eminent cancer researchers who appeared before you last year and who are on the cancer prevention committee of the international union—Dr. W. C. Hueper, Dr. William E. Smith, and Dr. Francis E. Ray. The committee has a letter from the American Cancer Society, also in support.

Mr. Chairman, it is appalling to think that 1 out of every 4 persons in this country will at some time or another suffer from cancer.

The part that chemical additives play in the cancer picture may not yet be completely understood, but enough is known to put us on our guard. The safety of the public health demands that chemical additives should be specifically pretested for carcinogenicity, and this should be spelled out in the law. The precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anticarcinogen provision.

I should also like to touch briefly on two or three other points.

For several years, experiments have been going on to find a way to successfully preserve food by the use of irradiation. While apparently this does not cause the food to become radioactive, I understand that it has not yet been determined what chemical reactions may result, and what the effect of those chemical reactions might be. Since irradiation may become accepted as a new method in the processing of food, in any legislation now being considered, it seems only prudent to include radioactive material in the definition of chemical additives. Both the FDA bill and H. R. 7798 do this.

Also, both these bills would cover chemical additives in feed given to animals destined for human consumption, and food derived from animals. The addition of stilbesterol to cattle feed and the use of antibiotics as additives in feed are now common practice. Urea, a synthesized product made from carbon dioxide and ammonia, is being used in increasing amounts in rations for food animals. Other chemicals are in similar use, and still others are being experimented with. There is a definite need to have these chemicals subject to any legislation dealing with food additives.

I believe it is not necessary for me to go into the appeal provisions of H. R. 7798. You have heard the views of Judge Biggs on the appeal provisions of the various bills, and I think the procedure indicated in my bill conforms in essential aspects to the recommendations of the Judicial Conference of the United States, which Judge Biggs represented.

Mr. Chairman, I have no exaggerated pride of authorship. I have tried to make H. R. 7798 a good bill, and I believe it is a good bill. But I do not consider it a perfect bill. If the committee can improve it, I shall welcome the improvements. What I have tried to do today

is to highlight certain provisions which I feel any food additive legislation should contain. I recognize that this is a difficult subject on which to legislate, and it is impossible to anticipate all contingencies but in my bill I have tried to give the public the maximum protection possible.

The public is deeply concerned with the food-additive problem and is increasingly aware of the issues involved. The letters which I continue to receive from people all over the country express this concern. The writers cannot understand why action has been so long delayed.

Certainly there is nothing of greater importance to any nation than the health of its people. I am confident that the committee shares this view, and it is my earnest hope that strong food additive legislation will be enacted in this Congress.

Thank you, Mr. Chairman, and gentlemen, for your courtesy.

Mr. DINGELL. On behalf of the committee I would like to thank you for a very fine presentation and compliment you for the very splendid job you have done in keeping this matter not only before the public. Your constituents should very well be proud of you. I think that the work that you have done in this field will most certainly reflect itself in the legislation which will be reported out of this subcommittee and out of the full committee.

I would like to ask if you would like to give the name of the gentleman who sat on your left during your presentation today.

Mr. DELANEY. This is Mr. Harris. He is my executive assistant and he probably at this time knows as much about chemical additives as any one layman in the Congress. He has answered the mail and sometimes it requires 5 or 6 hours of his time each day to answer the mail that is coming in from every part of this country.

It is a strange thing. We finished the investigation in 1952 and naturally you would expect that the mail would drop off after it was concluded. I will say that there is more interest shown today—this is some 6 years later—than when the hearings were being held back in 1950, 1951, and 1952. I think that the public is becoming increasingly aware of the importance of this legislation. May I point out to you, Mr. Chairman, that even in the State of New York they have proposed legislation to control chemical additives. It did not pass at this session. It was introduced too late. I spoke to the assemblyman and the senator in New York State who had proposed it. They told me that the bill had been assigned to them by the State administration.

I have been informed that there are at least a dozen other States that are considering legislation along these lines. I think that the food industries would help themselves to have a uniform Federal act so that they wouldn't be forced to meet different requirements in each of the States. It would certainly work out to their benefit.

Mr. DINGELL. Mr. Loser?

Mr. LOSER. I would like to associate myself with the remarks of the chairman with reference to the very fine statement of the distinguished gentleman from New York. I heard you, Mr. Delaney, when you testified last year and I was very much impressed by your statement about the bill, and your statement at this time has been splendid. I might say that some one has done a terrific job with reference to your bill because just this morning I received in the neighborhood of 40 letters and postcards suggesting its passage.

Mr. DELANEY. That makes me very happy, Mr. Loser.

Mr. LOSER. Those letters and post cards came from over the Nation outside of my State, from all over the Nation, and that has been happening for the past 2 weeks. As a matter of fact, it looks like I am going to have to get some extra help to answer the mail.

Mr. DELANEY. That is the way I felt for a long time, Mr. Loser. I want to say that the mail we get comes from every State in the Union, and how these people pick up the information is more than I can understand. Every letter is a sincere letter.

Mr. LOSER. We are very happy to have you here.

Mr. DELANEY. Thank you.

Mr. DINGELL. Mr. Bush?

Mr. BUSH. I just want to say to the Congressman I am very happy to have you here. I appreciate the sincerity you have in regard to this matter. It is something that is vital to all of us. We are all interested in it. It is legislation that is difficult to know the proper thing to do, but we must have something.

Mr. DELANEY. It has been a long grind, may I say, and sometimes one gets a little bit discouraged but I have tried to keep this thing alive.

Mr. BUSH. I commend you for a fine statement.

Mr. DELANEY. Thank you very much.

Mr. DINGELL. Dr. Neal.

Dr. NEAL. Mr. Delaney, whether you have pride of authorship of this bill or not, it doesn't matter.

Mr. DELANEY. That is right.

Dr. NEAL. Judging from what other members of the committee have said and from my own experience in my own office, I think that the people in the United States will recognize this as your measure whether it is ever passed as the Delaney bill or not. They know the effort that you have put into this.

I know you have given it a great deal of study. It will eventually, I think, make the public realize a lot more just what the potentials of this thing and regardless of any legislation I do not doubt, because of the fact that the public has been aroused to the possibility of additives in food, will in themselves make it almost imperative upon the manufacturers and processors of foods to be on their guard to see that they do not use certain things that might be deleterious to health.

Regardless of whether the bill is passed in your name or whose name, I think you deserve all the credit that has been given to you and I think you made a splendid statement.

Mr. DELANEY. Thank you, Dr. Neal.

Mr. DINGELL. Are there any further questions?

I would like to thank you again, Mr. Delaney.

Mr. DELANEY. It has been a pleasure indeed to have the privilege of appearing before this committee. I trust that you will be able to report a bill.

I do not think that any bill that would come out of this committee or any bill that we would pass on the floor would be complete in every way. It would probably take amendments from time to time, but lets get started on it. We will be doing a service for I think not only for the American public, but, I think, for the people of other countries.

Mr. RHODES. Mr. Chairman, I am very sorry that I was not present to hear Congressman Delaney. I have been honored in being host to

a group of very prominent citizens from my district. Just before coming in I was telling them that the greatest amount of mail I got in this session of Congress has come from people who are interested in the Delaney bill.

I want to commend Mr. Delaney for the work he is doing in this legislation.

Mr. DELANEY. Thank you very much, Mr. Rhodes.

Mr. DINGELL. Before the Chair recognizes Mr. Dunn, I would like to make mention of the fact that our very good and very dear friend and colleague, a member of this committee, a very valuable and a very hard working and extremely able Member of this Congress, Mr. Rhodes, for whom I have the highest personal regard and the greatest personal affection, and whose work on this committee has been of the utmost value, has a number of guests here in the room today, and at this point the Chair would like to recognize our distinguished friend and colleague who will introduce his guests to us.

Mr. RHODES. Thank you, Mr. Chairman, for your kind remarks.

The group that is here today visiting Washington is a political science class in adult education from Albright College in Reading.

Heading this group on the visit is Prof. Lewis C. Smith, a very prominent teacher at Albright. Mr. Smith taught my son and daughter, both of whom graduated from Albright College, one of the important schools of higher learning in Pennsylvania.

They are here visiting the Capitol and seeing from the inside how their Government works. They are especially interested in seeing a committee at work.

Mr. DINGELL. Mr. Dunn, I would like to make you welcome on behalf of the committee, sir.

STATEMENT OF CHARLES WESLEY DUNN, GENERAL COUNSEL, GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. DUNN. Mr. Chairman, I deeply appreciate the privilege which has been extended to me by Chairman Harris and Chairman Williams, and your good self to make a brief supplemental statement, in addition to what I said last July on this legislation.

As you will recall, I am general counsel for the overall national association of food manufacturers in this country, which includes the leading food manufacturers throughout the country.

I wish first to join what has been said by the members of the committee in addressing Congressman Delaney.

The food industry also congratulated Congressman Delaney on his pioneer leadership for this legislation.

We think he has rendered a great public service and we are very happy to recognize it at this time, as we have done before.

The reason I have come before you now is to make three additional observations.

I stated last July that the leading food manufacturers I represent endorse the principle of legislation to amend the Federal Food, Drug, and Cosmetic Act to require a safety pretesting of food additives, where this precautionary action is scientifically required or indicated.

The public health need for such legislation is unquestioned. Since the committee has its last hearings, there has developed a new need for this legislation.

That need is this: It is essential that we now have a Federal standard of legislation here as a model for uniform State and municipal legislation.

During the past year some States have initiated action to enact similar legislation. I reside in New York State. We had four bills for such legislation at Albany this year, recommended by Governor Harriman and his consumer counsel, Dr. Persia Campbell.

In addition, the city of New York now has before it a proposed municipal food law which will require a safety testing of food additives just as this legislation does from a Federal standpoint.

We favor State and municipal legislation as much as we do Federal legislation in this area. But the former legislation must be uniform with the latter legislation, in order that a food manufacturer may do an interstate business with the same standard product.

We had precisely the same situation in 1906 when the original Federal Food and Drug Act was enacted and we were confronted with State food and drug laws across the country which were not uniform. The only way that problem could be solved was to enact the foregoing act, which we call the Wiley Act, and its enactment did have the very result that was contemplated here, namely, of providing a basis for bringing the State laws into more or less uniformity.

I talked with Senator Hill, of Alabama, this morning, chairman of the Senate Committee on Labor and Public Welfare. He told me that, just as soon as the House passes this amendment, he will see that it is given immediate attention by his committee, and that he will take action to expedite its enactment by the Senate at this session.

You will, perhaps, pardon my adding a personal note here and mentioning again the fact that it was my privilege to make the first public recommendation of this amendment in an address before the American Chemical Society in 1948, and only this week I received an invitation from the American Chemical Society to address its annual meeting next fall at Chicago and to report what progress has been made in the past 10 years on this recommendation. I hope very much that I can report that Congress has enacted this amendment.

The second observation is this: We must not be under the impression that the problem of legislation to control the safety of food additives is exclusive to our country. For that is not so.

In the whole of our so-called free world and in the area of national food laws, there is no subject that is more discussed now than the enactment of this sort of legislation.

In short, we are here dealing with a worldwide legislative problem, and the time has come for our Federal Government duly to solve it in this country.

My third observation is this: Throughout these hearings you have received comments from many witnesses on how this legislation should be drawn. Our position is that you should start with the administration bill, which is H. R. 6747, as the basis for enacting the legislation before us. I said in my last statement that the food industry, which I have the honor of representing, endorses the policy of the administration bill. But we suggest that it should be revised to correct, simplify, and otherwise improve it.

Mr. LOSER. Mr. Dunn, didn't you testify last year on this same bill?

Mr. DUNN. Yes, sir, but these are additional thoughts.

Mr. LOSER. I thought that you had made those statements about the procedure and so forth in a prepared statement before the committee last year.

Mr. DUNN. You are quite correct.

Mr. LOSER. Your views about it are in the record, and unless you insist upon it, I don't believe that there would be any need to repeat it.

Mr. Chairman, he testified at length last year as I recall on this same bill.

Mr. DUNN. That is true. But there are certain additional comments I would like to make at this time. For example, we originally started with the position that the review of an adverse administrative opinion on a food additive should be on a de novo trial basis. But after listening to the testimony of Judge Biggs and after listening to the FDA we have abandoned that position; and we are willing to accept the review provisions in the administration bill, duly revised.

Mr. DINGELL. You are satisfied to accept those?

Mr. DUNN. Yes, sir, in that revised form. I said to the committee last year that I would study the testimony presented at these hearings and submit a suggested revision of the administration bill. I will soon forward this revision. It will substantially preserve the administration bill, except in the matter of functional value. We believe that if a food additive is safe, then the only question remaining is whether it is deceptive; and as here amended the Federal Food, Drug, and Cosmetic Act will outlaw any food additive that is either unsafe or deceptive. Dr. Bernard L. Oser, recently suggested in the Food, Drug, and Cosmetic Law Journal a compromise on this functional value question. His suggestion is that the functional value need only be shown where a food additive is of a kind that a safety tolerance must be established for its use.

At least that is his suggestion and it hasn't been put in the record.

Mr. DINGELL. I believe that is in the bill now, isn't it?

Mr. DUNN. No, that is not in the administration bill.

Mr. DINGELL. Thank you very much, Mr. Dunn, for a very fine statement. We are honored to have with us today another distinguished Member of the House of Representatives in this field who has been very outstanding.

At this time the Chair has the honor and privilege of recognizing our distinguished colleague the Honorable A. L. Miller, a Member of Congress from Nebraska.

STATEMENT OF HON. A. L. MILLER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEBRASKA

Dr. MILLER. Thank you very much, Mr. Chairman. I will be very brief.

I have been interested for a number of years in the question of pesticides and chemicals in food legislation. A few years ago I was on the so-called Delaney committee that went in considerable detail into the pros and cons of chemicals in food.

Any legislation that the committee adopts ought to be in the interest of the public and not in the manufacturers' interest or loaded on the side of the Food and Drug Administration.

Any chemical that is proposed for use in food as an additive of any type ought to first be tested as to its safety before it is permitted to be used, not used and then challenged afterward.

On the grandfather clause, which is always a controversial thing, that chemicals that are now in use, unless there is some challenge raised by the Food and Drug Division, might well be used without further testing unless there is some question about their safety. I believe some 250 chemicals out of 750 are being used but some may be in question. If they are suspect, evidence should be presented as to their safety.

I think there will be very few, however, if any, that would come into that category. I realize what I am to say now may have been presented before and is controversial. I am not sure that the Department agrees entirely and whether Mr. Dunn, whom I have known for many years, agrees, and we have talked about these things pro and con over the table. It is the question of what to do when industry and the Department differ with each other. Who is right and who is wrong.

We provide in the so-called Miller pesticide bill that there be an expert council set up of the top chemical experts who were I believe selected from the National Science Council, and they then would make a study of the chemical and their findings would be made to the Department and the industry involved. The findings are not binding, but would be a guide to the Department as to whether a chemical was safe. If they are not satisfied with that conclusion, then let them go to the courts. Let the courts use the evidence presented by the experts. It should have great weight in the final decision. There is some disagreement in this procedure but I feel they should be permitted to use the evidence and the findings of the expert board in the court as part of the court record and findings in order to come to a conclusion as to whether the product might be harmful or should be or should not be used in food.

There are many, many other facets to this legislation. It is a complex piece of legislation. It affects everyone of us. The country itself today, women's clubs and others, are aroused over improper evidence on chemicals. It is an explosive and emotional thing. I have been sometimes worried as to what might happen if something would go wrong in our food channels and we would get some toxic condition in there to make a lot of people sick. It could happen.

Personally, I am worried about what happens to some of these pesticides and the things that might be carried over into food. The Food and Drug Department and the Agriculture Department have things pretty well under control. Industry is doing a good job, however in a tough economic world—there is always someone who wants to cut corners.

I think the bill that I have introduced goes beyond the scope of the other bills in that it provides for the new chemicals and processes that come along.

I doubt if we have scratched the surface as to the new things that are going to come along in food perservatives, the use of the end products of the uranium, and the isotopes, and things of that type.

We ought to make sure that any legislation adopted will meet any foreseeable conditions that will develop. I think one difficulty with the present law is that it was not broad enough. It was not far seeing

enough to meet the emergencies of 700 or 800 new chemicals that bounced on us all at once, some of them known and some of them unknown.

The bill I have introduced provides for handling all new chemicals, all hormones, and so forth. It goes into the use of stilbesterol. It goes into the various estrogens and hormones used in the development of sheep, and cattle, and hogs.

It is a wide practice now in industry to give the pig, the calf or the sheep a hormone and get them on to the market much, much more quickly. Most of the chickens in the East now have a pellet injected into their necks to make them chemically sterilized. They grow fat and are on the market sooner—some interesting facts came from the hearings—mink growers claimed damages from feeding the heads of chicken to their mink. A bill in the House sought to pay damages to the mink growers of Illinois and Wisconsin. Why? Because the Agriculture Department had told them to feed the head and livers and entrails of chickens to their mink.

It was during wartime. It was done to save food. They did that. They claimed that those chickens had this little pellet stuck in the back of the neck and they didn't have any little mink. The mink were all sterile. That is how potent this drug is.

I personally held up the bill in the House for a number of years saying that the people who were using these ought to have known what the stibesterols and the other internal secretions would do to their mink, but it was a serious thing and they were hurt because of the sterility of the female or the male mink. So there is a wide, wide range and any legislation that you adopt ought to cover, it should be broad enough to cover the internal secretions and new chemicals that will come along like the isotopes and the estrogens and the other end products of several new developing ideas.

Mr. DINGELL. There is only one thing in your statement I want to object to and that is the last remark you made off the record about a doctor having himself as a patient. I think in your case I would certainly take issue on that.

Dr. MILLER. I have been treating myself for a week and I haven't recovered yet.

Mr. DINGELL. Mr. Bush?

Mr. BUSH. I want to say the Doctor has been, very helpful in giving us information, as to what should be done about this legislation.

It is complex, as you have said, but I do hope that we will come up with something.

Dr. MILLER. It will not be possible to pass legislation that industry will entirely like. Mr. Dunn's group will not like some things in the bill. Neither will the Food and Drug Administration, but I think it is our business as Members of Congress to get in between some place and make sure that what we do pass is in the interest of the public, not in the interest of the food industry or any particular group.

They are all right. They are a big group and they are doing a fine job in protecting the American public. If it was not so we would have some cases of poisoning now that would give us some unhappy situations.

Mr. BUSH. I think that is true. They have done a marvelous job.

Dr. MILLER. They have done a grand job.

Mr. BUSH. They are helping themselves and trying to see that whatever foods they are preparing are beneficial and safe for human consumption.

Dr. MILLER. I think that is true but we must remember that in a tough economic world there is always some shyster who wants to cut corners and when we do that we sometimes get into a position where you are hurting people.

Dr. NEAL. Dr. Miller, would you mind telling us have developments so far been able to show just what the effect on human beings has been from the consumption of foods from animals that have been artificially treated with hormones?

Dr. MILLER. I do not believe that there is any bad effect. We do know that animals show unusual growth. There were some on our committee, the Delaney committee, that wanted to outlaw the use of the pellets in the chicken necks. I think now most chickens that are sold, or a good many of them, on the market are chemically sterilized chickens.

I said then, and I am inclined to think now, that if I was a young man and expected to raise a family I would not live on a diet of chicken necks.

Dr. NEAL. After all, that same principle has been applied by certain protectionists for a long time.

Dr. MILLER. That is right.

Dr. NEAL. So far there is no bad effect.

Dr. MILLER. I don't think this has been any bad effect.

Mr. BUSH. Doctor, who wants to eat chicken necks?

Dr. NEAL. Thanks, doctor. I think you made a very fine statement.

Dr. MILLER. It is very short.

Dr. NEAL. I know that it is with humility that you discuss this matter as thoroughly as you have and represents a long period of your contact with the general public whom, as you say, we are here to serve first even though we have to recognize and give the industry a great pat on the back for the very successful things that have been done toward preservation and preparation for the human beings.

Thank you sir.

Mr. DINGELL. Thank you very much.

Dr. MILLER. Thank you very much.

Mr. DINGELL. Are there any other witnesses present in the room who desire to make any statement at this time? My colleagues will be happy to note then that this will conclude the hearings and any one desiring may have 7 days in which to file a statement.

The record will remain open for that period of time. This will conclude the hearings and the subcommittee will stand adjourned until the call of the Chair.

(The following material was submitted for the record:)

THE FUNCTIONAL VALUE OF FOOD ADDITIVES

By Bernard L. Oser, Ph. D., Food and Drug Research Laboratories, Inc.
Maspeth, N. Y.

Bills designed to improve regulatory control of food additives have been incubating in the laboratories of Congress for the past 5 years. So far the only law to hatch from this process has been the Miller amendment covering the use of pesticides. Failure to produce a corresponding law with respect to in-

tentional food additives may be attributed to both environmental and genetic factors. From the environmental standpoint it could be said that much light has been cast on the need for such legislation but perhaps not enough heat has been turned on. However the major difficulty has been genetic, i. e., unsuccessful cross-fertilization of germinal ideas within the regulated industries or between them and the Government.

It is to one of these controversial issues that I propose to address myself today; namely, whether functional value shall be assessed by the regulatory agency in considering the introduction of any new food additive. I foresee a real danger that industry's reaction of no pasaran to this proposal may lead to further delay in enacting a Federal amendment with the consequent threat of nonuniform State and local legislation.

There is no doubt that food additives are intended to serve some useful purpose. Every bill now before Congress defines additives in terms of intended use. The voices of the health officials, the medical professions, and the consumer have been raised repeatedly against the purposeless addition of any nonnutritive substance to foods. To suggest that this does not coincide with the view of responsible industry is to build a strawman. Food producers and processors have, in fact, invited closer regulatory control over useful food additives. The question with which we are here concerned revolves around whether this control shall be limited to the issue of safety or shall include also an evaluation of usefulness.

Without entering into a semantic discussion of the subtle distinctions between such terms as utility and functional value, let us examine how various agencies have expressed the concept that food additives must be useful. The Food Protection Committee of the National Research Council and the American Public Health Association have adopted the principle that "A decision to use an intentional additive in foods should be based on the assurance (*a*) that it will be safe, and (b) that it will benefit the consumer."[1, 2] The Joint FAO/WHO Expert Committee on Food Additives has taken a similar position in its report discussing the "circumstances in which there is technological justification for the use of acceptable food additives *to the advantage of the consumer*".[3] [Emphasis supplied.] Spokesmen for the Food and Drug Administration have expressed their views on this subject several times during the past year. At the congressional subcommittee hearing last year, Commissioner Larrick testified that "We think they (food additives) should be permitted only when there is some definite benefit to the producer or consumer to justify the risk involved."[4] This extension of the allowable benefit to the producer was repeated by Mr. William W. Goodrich, General Counsel for the Food and Drug Administration, when he stated that "Public opinion will be satisfied only by a rational justification based on considerations of food technology or consumer benefit coupled with assurance of safety of the proposed use."[5] He went on to interpret consumer benefit as including "a use which benefits him directly in terms of product improvement or food convenience, or indirectly in terms of improvement in food processing, storage, packing, or other steps in moving the food from its raw state to the dinner table." The view that technological advantage is included in the broad concept of consumer benefit was also expressed by Mr. W. B. Rankin, Assistant to the Commissioner, in a recent address before the Manufacturing Chemists Association.[6]

Probably the most extensive description of justifiable uses for food additives is contained in the FAO/WHO report cited above. Included are—

(*a*) Maintenance of nutritional quality, such as by the use of antioxidants.

(*b*) Enhancement of keeping quality or stability, with resulting reduction in food wastage, through the use of antioxidants, antimicrobial agents, inert gases, meat cures, etc.

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[1] Principles and Procedures for Evaluating the Safety of International Chemical Additives in Foods. Food Protection Committee, National Research Council, November 1954.

[2] Resolution of the American Public Health Association, November 7, 1957.

[3] General Principles Governing the Uses of Food Additives. Report of the Joint FAO/WHO Expert Committee on Food Additives, Rome, Italy, December 1956.

[4] Hearings before the Subcommittee on Health and Science, Committee on Interstate and Foreign Commerce, House of Representatives, 84th Cong., 2d sess., 1956.

[5] Goodrich, William W. The Rational Use of Chemicals in Foods. Food Drug Cosmetic Law Journal, 12, 535 (1957).

[6] Rankin, Winton B. Incidental Additives. Presented before the Manufacturing Chemists Association, December 2, 1957, Washington, D. C.

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(*c*) Enhancement of attractiveness of foods by means of coloring and flavoring agents, emulsifiers, stabilizers, thickeners, clarifiers, and bleaching agents. (That appeal to the eye as well as the palate is not a mere whim of the food producer, is recognized by all nutritionists, since proteins, vitamins, and minerals serve no purpose unless eaten.)

(*d*) Providing essential aids in food processing. Agents which function in this capacity include acids, alkalis, buffers, sequestrants, and various other types of chemicals.

(These and similar acceptable uses are also described in the publication 398 of the Food Protection Committee entitled "The Use of Chemical Additives in Food Processing.")

It is noteworthy that useful additives may accrue not only to the direct benefit of the individual consumer but indirectly to the benefit of the public generally, by conservation or enhancement of the food supply. Moreover enhancement of the nutritive value by means of an additive, be it a protective agent or a nutrient per se (such as a vitamin or amino acid) should be considered in terms of the food itself, not in terms of the diet as a whole. Whether or not such an additive is desirable from the standpoint of the nutritional needs of the population, should be determined under other administrative authority, and not be confused with the issue of the safety of food additives.

Highly significant is the emphasis placed by the FAO/WHO report on situations in which food additives should not be used. These include uses which disguise faulty, or careless, processing methods; which encourage unhygienic conditions of handling; which result in deception of the consumer; which cause substantial loss of nutritive value; or finally, "when the desired effect can be obtained by good manufacturing practices *which are economically feasible.*" [Emphasis supplied.]

Citation of the situations enumerated by the FAO/WHO committee in which food additives should not be used, would be incomplete without mention of the fact that existing provisions of the Federal law prohibiting adulteration and misbranding of foods provide ample protection against deception, filth, and depreciation of nutritive or economic value. It is not from this point of view that the consideration of functional value of food additives needs to be justified. The reference to good manufacturing practice recalls one of the objections raised to granting administrative authority to pass upon functional values; namely, that control over manufacture is beyond the scope of a public health measure so long as protection against adulteration and misbranding is assured. A good illustration of a situation that might arise, is to be found in the testimony of Commissioner Larrick concerning the possible use of formaldehyde in milk. Despite the fact that a harmless amount of this substance can function as a highly efficient preservative, its use would be prohibited on the ground that departure from "good manufacturing practice," viz, the use of refrigeration, pasteurization, sterilization, etc., should not be permitted. Were safety under conditions of use the only criterion, it seems unlikely that this use of formaldehyde could be prohibited from milk.

The argument that consideration of functional value would be an intrusion of the Government into control of technological practice overlooks the fact that the Food, Drug, and Cosmetic Act gives the Administrator authority to consider what constitutes good manufacturing practice, in relation to the presence of added poisonous or deleterious substances (sec. 406 (a)). Similar authority is exercised quite extensively in the promulgation of definitions and standards of identity of foods and, directly or indirectly, through factory inspection. If what constitutes good manufacturing practice can be given weight in situations concerning sanitation or honesty and fair dealing it seems not unreasonable that it may deserve attention in safety evaluations.

Since the Administration bill (H. R. 6747) contains practically all of the features to which industry witnesses have taken exception, let us examine how it takes functional value into account. In the first place a "chemical additive," by definition, must be intended to preserve or alter food or be used "for any other purpose in producing, manufacturing, packing, transporting, or holding food." (The definitions in all other bills contain a similar provision, except H. R. 8112 (Representative Miller) which describes use as "the intentional addition* * * for the purpose of imparting a desired quality to the food.") H. R. 6747 goes on to require not only a statement of the conditions of the proposed use (without which a decision as to the safety under conditions of use would hardly be possible) but "all relevant data bearing on the functional

value" of the additive. This is for the purpose of a later section which provides that the regulation permitting the additive shall not issue unless, inter alia, the administrative agency is satisfied that the "proposed use has functional value." An exception to this provision is made "if he (the Secretary) finds that such additive is not a poisonous or deleterious substance."

From what has already been said it seems reasonable to expect that the Food and Drug Administration intends to construe functional value broadly, to comprehend, in effect, any use which enhances the nutritive value, stability, acceptability, or economy of food, aids in its production or technology, or does not encourage unsanitary handling. The Administration has professed its willingness to depart from the present necessity rule as applied to poisons per se and to adopt the principle of safety under conditions of use, provided the additive is useful. However, the limitation of consideration of functional value to poisonous or deleterious additives provides no basis, other than the per se doctrine, for ascertaining whether or not a substance is exempt from such consideration.

Past experience tells us that very few additives, old or new, could escape being classified as poisonous or deleterious by the per se yardstick. If toxicological data obtained at a dosage level deliberately set high enough to induce an adverse response were to be used as the basis for defining a poison, practically all substances would fall into this category. But if the new approach to food additives is designed to replace this impractical per se doctrine with an alternative better geared to modern technological advancement, it will be necessary to delineate more clearly the special circumstances under which weight may be given to functional value. If these circumstances cannot be specified in the language of the statute they should at least be specified in the legislative history of the proposed revision of the law and not left to administrative or judicial interpretation.

For a full appreciation of the role of functional value in assessing the permissive use of food additives, it may be profitable to explore a bit some aspects of safety evaluation. As is often the case in discussions of this subject, we must remind ourselves that all things are relative; safety, necessity, and value, whether functional or otherwise, are terms which have no meaning in the absolute sense. In a paper published in 1953 in the Food Drug Cosmetic Law Journal, I elaborated on the thesis that poisons do not exist in a vacuum.[7] Similarly, safety or harmlessness are relative, regardless of how reasonably certain we may be of judgments derived from human experience or animal experiments. If we acknowledged that safety to all persons under all conditions can not be established with absolute certainty, it must be admitted that some residue of uncertainty remains. To minimize it, it is customary in the practical application of toxicological data, to allow a margin of safety. This is, strictly speaking, a margin for uncertainty and its magnitude is dependent on many factors. It presumably takes care of differences in susceptibility between species and strains of animals, and for variations in human response due to age, disease, dietary habits, or physiological stresses. Safety evaluations must take into account the nature of adverse effects induced by excessive dosage and particularly whether these are irreversible or cumulative. Fortunately most food additives are intrinsically provided with brakes or warning signals, in the sense that undesirable effects in flavor, appearance, or texture, or technological difficulties in processing, guard against their excessive use. In such cases, and especially when their toxicity is judged by animal tests is of a low order, it is not necessary to establish maximum limits or tolerances. On the other hand where sufficient built-in protection does not exist and the toxicological evidence justifies it, a maximum limit must be set on the use of the additive, the level being in the safe range but no greater than that needed to do the job. Implicit in such cases is the possibility that amounts above the tolerance may approach, if not enter, the hazardous zone.

In view of the existence of a residual risk, however small, the Food and Drug Administration in its bill has claimed the prerogative of weighing this risk against the advantage to the producer or consumer. The exception, where the "additive is not a poisonous or deleterious substance" is couched in language, which has proved so vague and impractical under the present law, that it should, in my opinion, be replaced with a more realistic criterion. It is suggested that only when the nature of the additive and the toxicity data are such as to require

[7] Oser, Bernard L. Can a Poison Exist in a Vacuum? Food Drug Cosmetic Law Journal, 8, 693 (1953).

a tolerance limit on its use, should functional value be a proper consideration in a safety evaluation. Through this approach, the rejection of a proposed use would be based not on alleged lack of utility but rather on the paramount issue of insufficient safety. And this would apply only to additives where the degree of safety under conditions of use required that quantitative limits be established. Any intended use, even if safe, which constituted adulteration or misbranding, could be nipped in the bud by warning the petitioner to this effect without confusing the issue with the safety of the food additive. Disputes concerning safety under conditions of use could be more readily resolved by experts or by the courts than can questions of functional value involving subjective or esthetic considerations, consumer preference, and the like.

The Food and Drug Administration has agreed to "support legislation that permits even poisonous chemicals to be used at apparently safe levels, provided that in such cases the chemical serves some function that warrants taking the minimal margin of risk." If FDA were to go a step further and define its terms more specifically, I think the present roadblock would be removed. In short, what are needed at this point are:

1. A comprehensive statement of acceptable functional value which might serve as the basis for regulations for the administration of a food-additives amendment. The FAO/WHO report could well be considered as a pattern for such a statement.

2. A substitute for the per se terminology in H. R. 6747 whereby substances "not poisonous or deleterious" are exempted from consideration of functional value. I submit that the latter should be limited only to such substances as require the establishment of maximum tolerances.

3. Finally, a clear understanding that rejection of a proposed food additive would not be based merely on its alleged lack of functional value, but on considerations related to safety for use under conditions of use.

May I conclude by suggesting somewhat belatedly, a better title for this paper: "The Futility of Fending Over Utility."

SUPPLEMENTAL STATEMENT OF L. S. HITCHNER, EXECUTIVE SECRETARY NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

We previously submitted a statement, copy attached, dated July 11, 1957, in which we reviewed the existing legislation applicable to pesticide chemicals used in the production, storage, and transportation of raw agricultural commodities. That legislation (Public Law 518, 83d Cong.) is commonly referred to as the Miller pesticide residue amendment and is now section 408 of the Federal Food, Drug, and Cosmetic Act. We pointed out that the first eight of the above enumerated bills contanied provisions to exempt from the proposed food-additive legislation pesticide chemicals subject to the Miller amendment. H. R. 10404 had not been introduced at the time and, hence, was not referred to in that statement. We also advised that, in some instances, the wording of the exemption was such that there could possibly be in the future some differences of opinion as to its interpretation and that we would submit suggested amendments to clarify the intent and scope of the exemption for pesticide chemicals.

We now respectfully submit the suggested amendments and some additional material intended to clarify and more clearly define the status of pesticide chemicals in relation to the pending legislation.

Three of the subject bills (H. R. 7700, H. R. 7798, and H. R. 1938) appear to require no amendments relative to pesticide chemicals; they define the status of the latter in an acceptable manner. The other six bills H. R. 366, H. R. 6747, H. R. 8112, H. R. 8390, H. R. 8629, and H. R. 10404) should be amended in this regard. Amendments designed to provide a uniform provision as regards pesticide chemicals are proposed. In order to fit the present text of each bill, the wording of the proposed amendments has been varied slightly.

The proposed amendments which we are requesting are based upon a provision in H. R. 6747, which was later incorporated into H. R. 8112, H. R. 8390, and H. R. 8629. Our proposal modifies the wording of that provision in one respect. The modification and the reasons in support of it are set forth in our comments on H. R. 6747, and, for brevity, are not discussed at this point.

The suggested amendments and explanations thereof are set forth in attachment A.

In an effort to clarify the status of pesticide chemicals under H. R. 6747 and the other bills with similar provisions relative thereto, we have had discussions

and correspondence with the Food and Drug Administration. A copy of a letter, dated June 13, 1957, from the Food and Drug Administration to our association setting forth their interpretation of H. R. 6747 in relation to pesticide chemicals is enclosed as attachment B.

We consider the interpretations in that letter reasonable and proper, and believe it desirable that they be reflected in the committee report on the pending legislation, in the even that the bill, or another bill with comparable provisions, is reported favorably. This would help to avoid future uncertainties and possible differences of opinion in interpreting certain provisions of the bill.

If any further explanation of our position or proposed amendments is desired, we would be pleased to submit same.

In conclusion, we express our appreciation for the opportunity of submitting these comments and hope that the committee will find them constructive and helpful.

NOTE.—The previous statement referred to appears on p. 111.

[Attachment A]

AMENDMENTS PROPOSED BY NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

H. R. 366

Amend page 2, line 7 by inserting after the word "commodity" the phrase "or a pesticide chemical to the extent that it is intended for use in the production, storage, or transportation of any raw agricultural commodity" so that the provision will read as follows: "The term does not include a pesticide chemical in or on a raw agricultural commodity, or a pesticide chemical to the extent that it is intended for use in the production, storage, or transportation of any raw agricultural commodity;".

Such an amendment is indicated by the fact that, in some instances, traces of pesticide chemicals used in the production, storage, or transportation of raw agricultural commodities will appear in processed foods prepared from such commodities. The present wording of this bill might be interpreted to the effect that, insofar as residues of the pesticide chemical appeared on raw agricultural commodities, the chemical was subject to the Miller amendment, and, to the extent that the residues later appeared in processed food prepared from the raw commodities, the chemical was subject to this bill. Under this interpretation, if the bill were enacted, many pesticide chemicals would be subject to dual jurisdiction under two laws with different provisions, procedures, and regulations.

The purpose of this proposed amendment is to make it clear that a pesticide chemical intended for use in the production, storage, and transportation of a raw agricultural commodity and, therefore, subject to the Miller amendment would not also be regulated as a "new food additive" under the bill.

This amendment would insert into the bill a provision similar to that proposed below for H. R. 6747, 8112, 8390, and 8629.

H. R. 6747

Amend page 2, line 17, by deleting the phrase "when intended solely for use" and substituting therefor the phrase "to the extent that it is intended for use," so that the exemption (lines 15–18) would read as follows: "(2) Such term does not include (A) a pesticide chemical in or on a raw agricultural commodity, or a pesticide chemical to the extent that it is intended for use in the production, storage, or transportation of any raw agricultural commodity;".

This amendment is indicated by the fact that many pesticide chemicals used in the production, storage, or transportation of raw agricultural commodities have other uses. Some of these may involve processed foods but others do not. To the extent that a pesticide is added to processed food, it may properly be regulated as a "chemical additive" or "food additive." However, since its use on raw agricultural commodities is already regulated under section 408 of the Food, Drug, and Cosmetic Act, the Miller amendment, that use should not again be regulated under this bill. Moreover, the fact that a pesticide chemical has a nonfood use in addition to a raw agricultural commodity use should not subject it to the bill. Both these interpretations are possible since the present wording of the bill exempts "a pesticide chemical *when intended solely* for use in the production, storage, or transportation of any raw agricultural commodity." [Italic added.]

To clarify the intent of this provision, we recommend that a pesticide chemical be exempt from the bill "to the extent that it is intended for use" in the production, storage, and transportation of any raw agricultural commodity. Such use is now regulated by the Miller amendment and the proposed amendment would eliminate any possible conflict or duplication of controls under two different sections of the Food, Drug, and Cosmetic Act as regards that use.

H. R. 8112

1. Amend page 2, line 9, by deleting the term "pesticide" and inserting in lieu thereof the term "pesticide chemical."

2. Amend page 2, line 10, by deleting the term "pesticide" and inserting in lieu thereof the term "pesticide chemical."

3. Amend page 2, lines 10–11, by deleting the phrase "when intended solely for use" and substituting therefor the phrase "to the extent that it is intended for use."

The first two amendments are technical in nature. While the term "pesticide" is commonly used, the Food, Drug, and Cosmetic Act defines and uses the term "pesticide chemical."

The third amendment is identical to that proposed to H. R. 6747 and is supported by the same considerations.

H. R. 8390

Amend page 2, line 12, by deleting the phrase "when intended solely for use" and substituting therefor the phrase "to the extent that it is intended for use."

This suggested amendment is identical to that proposed to H. R. 6747 and is supported by the same considerations.

H. R. 8629

Amend page 2, line 12, by deleting the phrase "when intended solely for use" and substituting therefor the phrase "to the extent that it is intended for use."

This suggested amendment is identical to that proposed to H. R. 6747 and is supported by the same considerations.

H. R. 10404

Amend page 2, line 6, by inserting after the word "commodity" the phrase "or a pesticide chemical to the extent that it is intended for use in the production, storage, or transportation of any raw agricultural commodity" so that the provision will read as follows: "The term does not include a pesticide chemical in or on a raw agricultural commodity, or a pesticide chemical to the extent that it is intended for use in the production, storage, or transportation of any raw agricultural commodity,".

This suggested amendment is identical with that proposed to H. R. 366 and is supported by the same considerations.

[Attachment B]

DEPARTMENT OF HEATH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D. C., June 13, 1957.

Mr. J. A. NOONE,
National Agricultural Chemicals Association,
1145 19th Street NW., Washington 6, D. C.

DEAR MR. NOONE: We are answering the questions raised in your letter of June 12, 1957, about the provisions of H. R. 6747 and S. 1895, in the order in which they were asked:

Question

1. Under these bills, what is the status of a residue in a processed food resulting from the application of a pesticide chemical to a raw agricultural commodity during production, storage, or transportation:

(*a*) When the residue is within the numerical tolerance or exemption established for the pesticide chemical on the raw agricultural commodity?

(*b*) When the residue exceeds the tolerance established for the raw agricultural commodity?

Are such residues to be considered and regulated as chemical additives?

Answer

1. (*a*) The situation here is covered by the proviso in section 4 of the bills which reads: "*Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such proceed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity."

(*b*) Food containing the excessive residue would be adulterated unless a tolerance has been established under the proposed section 409 and the residue remaining is within this tolerance.

The answer to the last question under No. 1 is given below under question No. 2.

Question

2. Does the fact that residues may result in a processed food from a raw agricultural use for which a tolerance has been established under the Miller pesticide residue amendment make a pesticide chemical a "chemical additive" within the meannig of these bills and subject to regulation under them, if enacted? Is such a pesticide chemical to be considered a "food" within the meaning of proposed section 201 (f)?

Answer

2. A residue in the processed food would be a chemical additive and of course the food would be regulated on this basis. But the pesticide chemical itself, as shipped by the pesicide manufacturer, would not be a chemical additive under the circumstances described, nor would it be considered a food. (See proposed section 201(s) (2)(A) in section 2 of the bills.)

Question

3. Pesticide X is recommended and sold for pest control in a food processing plant. It bears directions for use which will preclude contamination of the food, if followed. Assume for purposes of discussion that the recommended precautions to avoid contamination are not followed and that some trace of the pesticide gets into the food. Under these circumstances, would the pesticide or ingredients thereof be considered "chemical additives" and subject to the bills?

Answer

3. This is really 2 questions and can best be answered in 2 parts. The pesticide, bearing directions for use which will preclude contamination of food, if followed, would not be a chemical additive as shipped by its manufacturer.

If a food processor deliberately misused the pesticide so that food became contaminated with illegal residues, the stock of pesticide in the processor's possession would become a chemical additive. But this would not make other stocks of the pesticide become chemical additives, and it would not require the pesticide manufacturer who had no responsibility for the misuse to get his pesticide cleared under the chemical additives bill.

Question:

4. Section 201 (q) of the Federal Food, Drug, and Cosmetic Act as enacted by the Miller amendment provides that "The term 'pesticide chemical' means any substance which, alone, in chemical combination or in formation with one or more other substances, is an 'economic poison' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U. S. C., secs. 135–135k) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities." Certain agricultural chemicals used in the production, storage and transportation of raw agricultural commodities, such as defoliants and nematocides, are not now subject to the Federal Insecticide, Fungicide, and Rodenticide Act, or the Miller amendment. They would be subject to H. R. 6747 and S. 1895. Assume that one of these bills is approved in its present form, covering these materials, and that at a later date an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act is enacted making these products subject to that act and the Miller amendment. Under these circumstances, would residues of such agricultural chemicals on raw agricultural commodities be subject to regulation under the Miller amendment or the "chemical additive amendment" of both?

Answer:

4. Tolerances for the residues would be established under the pesticide chemicals amendment, and not under the chemical additives amendment. Of course this would give the same degree of consumer protection.

The above answers are all based of course upon H. R. 6747 and S. 1895 as they were initially introduced. If a chemical additives amendment is enacted, our interpretation and the administration of it will be based upon the language of the law as finally passed and upon the wishes of the Congress at the time it passes the law, as evidenced by committee reports or other legislative history.

Sincerely yours,

W. B. RANKIN,
Assistant to the Commissioner.

NEW YORK, N. Y., *April 2, 1958.*

Hon. CHARLES A. WOLVERTON,
House Office Building,
Washington, D. C.:

Can you see me on April 14 or otherwise early on April 15 before April 15–16 hearings on food additive amendment of Federal Food Drug and Cosmetic Act, for after such final hearings House Commerce Committee must determine its form of this amendment which I wish to discuss with you. After careful review of previous hearings record and long study of basic legislative question here presented I am now completing revised draft of this amendment in what I believe is its right form from standpoint of all concerned which duly revises its prior FDA draft and satisfies proper industry objections thereto; and which is therefore sound compromise draft that is equally fair to consuming public and regulated industries. As you know I represent major overall national association of leading food manufacturers of every kind throughout country but I have written this compromise draft of such amendment from a duly balanced standpoint. Please telegraph collect whether you can then see me for this brief discussion designed to aid committee in appropriately writing such amendment needed to protect public health and to provide Federal basis for uniform State law also now needed.

Thanks and regards.

CHARLES WESLEY DUNN.

RESOLUTION

Whereas the Federal Food, Drug, and Cosmetic Act requires that if a food product bears or contains a chemical preservative, its labeling must declare the identity and presence of the chemical preservatives when practical, and

Whereas we believe the public is entitled to this information: Now, therefore, be it

Resolved, That the Association of Food & Drug Officials of the Southern States, comprising the States of Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Texas, in annual conference, this the 10th day of April 1958, urges that no legislation be enacted which would exempt food products from these requirements; and be it further

Resolved, That the secretary of this association immediately forward a copy of this resolution to the Honorable Oren Harris, chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D. C.

V. E. STEWART,
Secretary-Treasurer, Association of Food & Drug Officials of the Southern States.

CORN PRODUCTS REFINING CO.,
New York, N. Y. February 10, 1958.

Hon. OREN HARRIS,
Chairman of the Interstate and Foreign Commerce Committee,
House Office Building, Washington, D. C.

DEAR CONGRESSMAN HARRIS. It gives me great pleasure to write to a fellow Arkansawyer. I am from Little Rock, though I have lived and practiced law in New York for over 25 years.

During the past 8 years, there have been a number of bills introduced on food additives and a number are now pending in this Congress before your committee. H. R. 10404 is by far the best bill I have seen from many standpoints, and to me as a lawyer it makes a great deal of sense.

I very much deprecate the "scare" approach to this subject that has been underlying the whole matter since it originally came up at the time of the Delaney committee hearings now so long ago.

I am enclosing a copy of an excerpt from a paper that I gave at the New York State Bar Association meeting on January 29, 1958, from which you may gather that from a safety standpoint I do not regard the legislation as urgent. There has not been, and is not likely to be, any scandal as regards the safety of our basic food supply. I think that all of the material that has been published to the contrary is a grave distortion of fact.

H. R. 10404 procedurally is simple because it fits in with industry practice at the present time.

The food industry is the largest industry in the United States and is estimated, on the basis of prices paid by consumers, to be about a $70 billion industry at the present time. In view of this fact and the thousands of manufacturers in the field, I am sure that your committee will at least give a fair hearing to the viewpoint of such a numerous and important industry.

Many of us feel that the procedures which are applicable to the comparatively much smaller drug industry are not at all practical when applied to an industry the size of the food industry. For instance, requiring a large amount of administrative work on all present additives would be a much more gigantic undertaking than the Food and Drug Administration realizes. The answer would be either a very large and almost impractical expansion of food and drug organization at a budgetary cost that is unnecessary and would not be desired by anybody, or a number of steps backward during the years the administrative log jam is being straightened out. I do not believe the Food and Drug Administration has been cognizant of all the implications of the various issues on which it has in good faith been too unyielding.

The fact that Food and Drug has not been willing to yield on any of the minor issues involved in this legislation over a period of years argues considerably against the urgency of having all the provisions Food and Drug wants enacted immediately. Congress might be more economyminded and wiser to start with legislation that conforms to industry practice, and if it does not prove to be satisfactory (as many of us feel it will), adidtional provisions can be enacted.

About H. R. 10404, Food and Drug undoubtedly will not be satisfied with the grandfather clause. They are certainly acquainted with almost all the additives that are now being used and there would be no objection to the bill excepting by name from the grandfather clause any additives Food and Drug deems to be of doubtful safety.

H. R. 10404 provides for enforcement by injunction. My best judgment is that if the new bill were enacted, there would be no injunction cases other than cases which the Food and Drug Administration would bring under the present law. For this reason, I do not think that the judicial views as to the burden of undertaking to handle increased litigation should have any weight at all in considering this bill.

There are several considerations that make legislation desirable from the standpoint of the whole industry; for instance, it seems desirable to get away from the per se provisions of section 406 in the case of additives which have been adequately tested for the use for which intended.

A number of States have legislation now pending, and it is far more desirable to have Federal legislation on which State legislation can be patterned than to have 48 different sets of requirements.

I am sure that you are interested in having the views on this legislation of companies which have a large interest in the legislation. If my client has any further information that the committee wishes, I would be happy to furnish it.

I am sending a copy of this letter and enclosure to each of the members of your committee, including Congressman Williams, who introduced H. R. 10404.

I would like to ask that this letter be made a part of the record of the current proceedings before your committee on food additives.

Sincerely,

SAMUEL A. MCCAIN, *General Counsel.*

Some Comments on Food Additives

Excerpts from a paper, On the Food Law, Some Landmarks along the Development of the Food Law and Its Administration since World War II, Given by Samuel A. McCain,[1] member of the New York Bar, at a Meeting of the Food, Drug, and Cosmetic Law Section of the New York State Bar Association, on January 29, 1958

FOOD ADDITIVES

A paper on food-law landmarks would be incomplete without some reference to food additives legislation, which has been the subject of so much discussion and writing since 1950. It do not intend to add one word to the discussion of this legislation, but at the same time I would like to set forth a few facts to contradict some of the scare headlines that appear whenever the subject is discussed, as it may be at this session of Congress.

A substantial part of our food supply consists of branded foods in packages, which are nationally advertised. These are the staples on the grocery store shelf.

If you represented a supplier of ingredients to food manufacturers, as I do, you would know that none of these manufacturers adds an ingredient to his product without exhaustive tests, both technical and analytical, as well as consumer acceptance and marketing tests, irrespective of the merits. Why is this?

I asked the package sales manager and the advertising manager of my principal client to estimate how much of a capital expenditure would be involved in placing an easily marketed product on most of the grocery store shelves in the United States. The answer was at least $5 million, and probably 2 or 3 times that amount.

On the same authority, in the 1920's, the number of items on the grocery store shelf averaged around 500; today, the average number of items is around 5,000. Because of the terrific competition for the golden foot of shelf space, for every new branded product that is successful, a number fail, and such new product must knock off the shelf an established oldtimer. Each new brand must maintain a reputation as untarnished as that of Caesar's wife; if sales slow up, it comes off the shelf and off the market. Millions of dollars will be required to repair the damage.

I just don't believe that fly-by-nights have the means to stand this kind of competition, and even if they did, self-interest would make them walk by day as slowly and carefully as their competitors.

Unintentional additives to perishables such as fruits and vegetables have now been covered, so far as safety is concerned, by the pesticide amendment, and the leading semi-perishables, bread, processed dairy products, and meat products, are subject to rigid standards.

The items mentioned above comprise practically all of our basic food supply.

I sincerely hope that any discussion of food additive legislation can be approached in an objective way in Congress, without any scare headline by products totally lacking justification in fact to cause public concern as to the safety of the Nation's food supply.

Statement of National Farmers Union

My name is Richard Shipman, and I am coordinator of legislative services for National Farmers Union. I speak on behalf of James G. Patton, president of National Farmers Union and the 750,000 voting members of our organization to urge approval of H. R. 7798.

Because we farm people play such a prime role in the production of food for the Nation and because, like all other members of society we are also consumers, we are deeply concerned about the bills now before your committee to strengthen the Federal Food and Drug Act.

For a number of years we have had resolutions from our State organizations, as well as the national organization, urging that the laws giving the Government power to protect the health of the consumer be strengthened, and that adequate appropriations be made available to administer these laws, and to carry on research.

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[1] The paper was not given in a representative capacity, but the writer is chairman of the food law committees of the American Bar Association and the New York State Bar Association, and general counsel of Corn Products Refining Co.

Following the startling disclosures of the Delaney committee investigations, the Montana Farmers Union convention went on record as follows:

"Eminent scientists have testified that there is evidence that cancer and other dread diseases might result from the ingestion, over the years, of even such small amounts of toxic chemicals as are now being used extensively in everyday foods such as bread, cakes, cereals, fruits, vegetables, milk products, and ice cream. Of particular concern to the farmer as a producer, as well as a consumer, is the fact that many of these dangerous chemicals are being substituted for valuable food substances such as milk and fats in bread products.

"We hold that the interests of the American people would be best served by changes in the Federal Food, Drug, and Cosmetic Act which would provide—

"1. For complete informative labeling of all food products.

"2. That no chemical to be used in the processing of until it has been proven that its consumption is entirely harmless to man.

"3. That sufficient money should always be available to the Food and Drug Administration to enable it to, (*a*) enforce the revised laws effectively, (*b*) enable it to undertake extensive research into the properties of chemicals used or to be used by food processors, and (*c*) to enable it to set up standards for interstate commerce.

"4. Nonnutritive chemicals should not be substituted for proved nutritional food factors, and encouragement should be given to the introduction and use of healthful ingredients such as milk solids, fats, wheat germ, soya meal.

"5. All toxic chemicals now in use should be immediately discontinued."

Because of the investigations of the Delaney committee and the reports of National Institutes of Health of the Public Health Service, the people are becoming generally aware of their peril from unregulated distribution and use of food additives which may cause cancer or other maladies.

It has become all too apparent that the public cannot depend for its safety on the processors of food products and the manufacturers of chemical additives. The Senate Judiciary Committee studying concentration in American industry has recently indicated the growing concentration of output in a few great manufacturing concerns. It becomes apparent the whole American people could be poisoned very easily by one unscrupulous manufacturer through its farflung distribution system. For instance, of the chemical industries making inorganic color pigments (among the chemicals most dangerous in causing cancer) four large companies produced 65 percent of the total output. It must be apparent that 1 or 2 dangerous chemicals coming from this highly concentrated production, constitute a tremendous hazard to the whole American people.

There has been evidence before this committee which leads us to believe that our large manufacturing concerns cannot adequately protect the public because of the limitation of the profit motive. This is a conclusion we must reach when a group of top research people lose their positions as a result of refusal to keep quiet about their findings concerning carcinogens. When one man is fired because of his research in cancer causing drugs it might be incidental, but when a number lose their jobs, one begins to believe there may be a conspiracy to keep the people ignorant about the cancer causing drugs which are being used in foods.

One has only to have heard the evidence before the Holifield committee about the danger of atomic radiation or to have listened to the controversy over cigarette smoking as a cause of cancer, to know that there can be a vast difference of opinion among even our most eminent scientists as to what does or does not constitute a danger to the public health. For this reason it is important to place the Food and Drug Administration of our Government in as string a position as possible in order that it may supply the protection our citizens require. It will require, in our opinion, at least the authority provided by H. R. 7798.

After listening to the testimony of the panel of scientists before this committee (many representing our largest chemical industries) one is impressed with what they say they do not know, more than with what they claim to know. However, one fact emerges—it requires a highly trained team of scientists, specialists in many fields, to give independent judgments of what is at best a calculated risk. We believe this can best be accomplished by the United States Department of Health, Education, and Welfare. Again, we respectfully urge passage of H. R. 7798 as the minimum authority.

Although farmers are in a sense scientists, because of their continuing role in carrying out the experiments of scientific farming, they are in no way equipped to know the danger to themselves or to the public of the chemicals which they may use in producing food. However, they are under great competitive pressure to keep up to date and stay in business. Therefore, they use every means to accomplish better and more production at lower cost.

The farmers are told by Mr. Benson, Secretary of Agriculture, that the answer to their low income predicament is to become more efficient—to "grow 2 blades of grass where 1 grew before," to feed scientifically and grow bigger and better chickens in half as much time with less feed. They therefore buy and experiment with almost any compound which manufacturers and advertisers promise them can aid in their battle for greater production at lower cost. This plainly is dangerous to the consumer and farmer alike.

We are aware that this fundamental competitive drive is inherent in the whole economy and although it may produce some startling results production-wise, it also carries with it a peril for the whole Nation. Plainly, previous testing by the Food and Drug Administration is indicated.

We wish to thank the committee for the privilege of submitting this statement.

MILLERS' NATIONAL FEDERATION,
Washington, D. C., January 31, 1958.

Hon. JOHN BELL WILLIAMS,
Chairman, Health and Science Subcommittee, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: We have been informed that your subcommittee will hold further hearing on proposed legislation dealing with food additives on February 4 and 5.

Like other major food industries, including the baking industry, we are vitally interested in protecting the integrity of the basic foods we produce. While the use of food additives is not as widespread in the flour-milling industry as it is in other food industries, we are nevertheless deeply concerned with the safety of those additives which are used in flour and other wheat food products.

The flour-milling industry, therefore, has given close attention to the problem of the use of food additives generally and particularly in our own industry. We have studied proposed legislation dealing with this problem during the past 5 or 6 years. We have appeared before your subcommittee to express our views and I direct your attention and that of your subcommittee to the testimony of our general counsel, Mr. Glenn G. Paxton, when he appeared in person in January and February of 1956. We believe Mr. Paxton's testimony at that time completely sets forth the position of the flour-milling industry in this matter and, therefore, we do not feel it is necessary for us to appear before your committee in person again.

We have analyzed all of the bills which have been introduced in the 85th Congress on this subject, which are now before your committee for consideration. It is our opinion that the bill introduced by Representative Joseph P. O'Hara, H. R. 366, is the one which will be most effective in accomplishing the objectives which our industry is seeking. We believe it combines maximum safeguards for public health with a minimum surrender of economic freedoms, without discouraging continued scientific progress in nutrition and in food technology to promote greater variety and wider distribution of foods for the consuming public.

In behalf of the milling industry, therefore, I wish to endorse the O'Hara bill and recommend it to the favorable consideration of your committee.

We have studied carefully the testimony before your committee of Mr. George Faunce, Jr., in behalf of the American Bakers Association on July 23, 1957. We find ourselves quite in accord with his testimony with respect to the O'Hara bill. We note also, his comments on H. R. 6747, introduced by Representative Oren Harris. We find ourselves in accord with his favorable comment with respect to some portions of this bill as well as with his criticisms of other portions.

If, therefore, as Mr. Faunce suggests, your committee decides to use H. R. 6747 as the basis for legislation, we would strongly urge your committee to adopt the changes and amendments which Mr. Faunce suggests.

I will appreciate it very much if you will accept this letter and the statements it contains in lieu of a personal appearance before your committee, and include it in the printed record of the hearings.

Respectfully yours,

HERMAN FAKLER, *Vice President.*

NATIONAL CANNERS ASSOCIATION,
Washington, January 30, 1958.

To the Chairman, Members and Staff of the House Committee on Interstate and Foreign Commerce:

Following is the text of a resolution dealing with the subject of food additives and supporting the principles contained in the indicated bills which was unanimously adopted by the canning industry at the annual meeting of the National Canners Association at its convention in Atlantic City on January 20.

FOOD ADDITIVE LEGISLATION

The public interest requires that every new food additive, whose safety and wholesomeness has not been determined, be adequately pretested prior to use. While the present or potential use of untested food additives is not an immediate problem for the canning industry, this association, as a responsible segment of the food industry, favors the enactment of sound legislation to insure adequate pretesting. It vigorously opposes any administrative licensing system for new food ingredients as contrary to the basic structure of the Federal Food, Drug, and Cosmetic Act and as creating unwise and unwarranted impediments to technological improvement. It opposes any administrative control on the basis of the functional value, as distinguished from the safety, of what the American consumer may eat. It insists that there be realistic and fair court review of administrative action asserted to be unfounded or unlawful. The association urges upon the Congress the prompt enactment of sensible, constructive legislation as exemplified in the Harris bill, H. R. 8390, and the Wolverton bill, H. R. 8629, as affording abundant public protection and yet avoiding any system of unfettered licensing or bureaucratic control of the American diet.

Very truly yours,

CARLOS CAMPBELL.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D. C., February 4, 1958.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science,
Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. WILLIAMS: We appreciate your letter of January 22, 1958, giving us an opportunity to comment on Mr. John A. Gosnell's letter of January 17 about food additive legislation.

We do not understand Mr. Gosnell's views on the cost of research to establish the safety of a new additive. All of the bills presently before your subcommittee contemplate essentially the same toxicity testing of proposed additives, and all provide that the results of the testing be submitted to our Department for evaluation before the chemical is added to food.

Mr. Gosnell comments also on the procedure to be followed once the scientific data are submitted. He recommends "the principle of notification," and supports either H. R. 366 or H. R. 8390. Under this procedure a manufacturer would submit data bearing on safety of an additive to our Department, and then even though the Secretary issued an adverse ruling, the manufacturer could use the additive after giving advance notice of his intentions. (Under H. R. 366 the additive could be used after 60 days' prior notice to the Secretary unless the Secretary instituted an action for declaratory judgment and so notified the defendant; under H. R. 8390 the additive could be used after 90 days' prior notice to the Secretary unless injunction proceedings were instituted by the Secretary and a restraining order or temporary restraining order were issued by the court.) The notification procedure would provide for a de novo trial of the scientific issues before a district judge or before a district judge and a jury.

Our views on the notification procedure and the accompanying de novo trial procedure are stated in considerable detail in the Secretary's letters of July 12, 1957, and August 16, 1957, to the committee on H. R. 366 and H. R. 8390, respectively. Last summer, Chief Judge John Biggs, Jr., testified on behalf of the Judicial Conference of the United States in opposition to the de novo trial procedure.

Briefly the principal reasons this procedure appears undesirable are:

1. No weight would be attached to the administrative evaluation of an additive. The procedure would give no effect, except a delaying effect, to an adverse safety evaluation by the Secretary.

2. As a practical matter, the Secretary would be required to sue in a district court if the sponsor gave notice that he intended to market an additive or a food containing it in the face of adverse evaluation. The burden of proof would rest on the Government to show that the additive is unsafe or that it has not been adequately pretested.

3. While issues coming before courts sometimes do involve subsidiary technical or scientific questions, these do not approach in complexity or resemble in nature the issues involved here and do not call for making a judgment as to the safety of a food additive in the light of man's total diet over a life span, and considering the whole population involved. Moreover, such a decision involves essentially a policy judgment as to the margin of safety that should be required for the protection of the public health. Such a policy judgment is appropriate to the rulemaking rather than the judicial function.

4. The procedure involved would be extremely burdensome and costly for private litigants, the Government, and the courts.

We believe that better and more economical public-health protection can be achieved by the procedure outlined in H. R. 6747. This would forbid the addition to food of a chemical additive, not generally recognized as safe, until the Secretary had reviewed available scientific data and had determined, and stated by regulation, the conditions under which the additive might be employed safely. Controversies with regard to regulations would be resolved by procedures now provided in the Administrative Procedure Act and the Food, Drug, and Cosmetic Act. And questions of science could be referred, in appropriate circumstances, to an advisory committee of experts selected by the National Academy of Sciences, a method that has been used successfully in administering the Pesticide Chemicals Amendment (Public Law 518, 83d Cong.).

When Assistant Secretary Elliot L. Richardson and I testify on the proposed legislation, we will be glad to explain the Department's views in greater detail.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

NATIONAL SMALL BUSINESS MEN'S ASSOCIATION,
Washington, D. C., January 17, 1958.

Re food additive legislation.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science, House Interstate and Foreign Commerce Committee, House Office Building, Washington, D. C.

DEAR MR. WILLIAMS: In all probability far too much has been said on this subject. In the interest of sound public administration, we wish only to call your attention to these compelling facts:

1. In 8 years of hearings on this subject no evidence has been submitted to establish the public necessity for the degree of regulatory control sought in H. R. 6747.

2. The cost of research is extremely high even when limited to that dictated by sound judgment. Since safety and adequate testing are matters of opinion, bureaucratic control (as in H. R. 6747) of the research required will add a tremendous cost to the national food bill, and will present an impossible barrier to small business.

We respectfully submit that the principle of notification is all that is required in the public interest to supplement the present law. We, therefore, support either H. R. 366 or H. R. 8390. The alleged burden on the district courts under these bills is, in our opinion, negligible.

We enclose, in case you have not seen them, several authoritative and cogent articles and editorials on this subject from Food Engineering.

Sincerely,

JOHN A. GOSNELL, *General Counsel.*

[Reprinted from Food Engineering, December 1957]

ELEVEN QUESTIONS BLOCK ADDITIVE BILL

By Russell S. McBride, Editorial Consultant, Food Engineering, Washington, D. C.

SEVEN POINTS SEEM CLEARLY ESTABLISHED BY GOVERNMENT HEARINGS. ELEVEN OTHERS WILL BE CONTROVERSIAL WHEN HEARINGS RESUME. MUCH HANGS IN THE BALANCE

Is future progress through new and improved food-product formulations to be impeded by an additives amendment to the Federal food law?

Here, much depends upon the provisions written into the amendment. And what goes into it will be decided in the settling of controversial issues. Let's look at the score—

The 1957 series of hearings held by a subcommittee of the House Committee on Interstate and Foreign Commerce substantially advanced the legislative situation on the subject of food additives.

Those hearings apparently established some clear, accepted viewpoints—while disclosing where divisions of opinion occur on others.

Generally accepted ideas

The following points are somewhat of an oversimplification, but still they are a properly significant statement of the present status.

1. Food additives, both natural and synthetic, have long been used and have contributed to superior food supply. Continued use, including proper new additives, is desirable for the general public benefit.

2. Preventing development of proper new additives and their use would restrict further progress. Also it would seriously reduce research incentive.

3. The use of food additives deserves control by new legislation in order to insure full public protection and safety.

Needed: Careful studies, prior to the new hearings, of who will support what—in order to judge tactics and gage prospects of each major point at issue

4. Pretesting of each new food additive should be required. This will make compulsory and general the present precautionary practice of most chemical makers marketing such materials.

5. FDA should have opportunity promptly to review all proposed new food additives. To make that review practical, the proponent of a new additive should notify FDA of his plans to use the material commercially, before initial commercial distribution of such additive or of a food containing it.

6. The scientific panel nominated by the National Academy of Sciences has described present testing for health and safety effects when these materials become diet components. Well recognized methods are in wide use. The skilled planning of such tests and their interpretation is necessarily based on the judgment of the professional workers involved. This requires persons skilled and experienced in testing and interpretation of test results.

7. Any idea that absolute safety can be guaranteed is wrong. Regardless of the skill and care taken, it is almost impossible to guarantee absolute safety on the basis of any pretesting. However, it is entirely practical to discover any significant hazard to public health, and thus eliminate it by proper pretesting.

True, these seven conclusions might not get absolutely unanimous support. But they seem to be clearly established facts and findings supported by the vast majority, including virtually all well-informed persons in industry, Government, and academic positions, who are acquainted with the food additive problem.

Uncertain conclusions

In contrast, there are 11 other findings which, though they have quite general support, still pose some differences of opinion, usually based largely on fears, not actual experience. Here are these 11:

1. There are very few, if any, cases in which food additives have caused any public hazard. Published opinions which claim hazards have almost always been traced to fears and not actual cases.

2. FDA review of proposed new food additives may or may not be supplemented by that agency's prior approval of each new formulation. At least two groups support the idea that FDA should have and should always exercise the authority of approval before first commercial distribution.

These two groups are: (*a*) those who think that the public is entitled to such protection in all cases, and (*b*) those who appear to want the Government to take or share the responsibility for such decisions, perhaps for the legal protection of the sponsor of a new additive if it later proves dangerous.

3. A considerably larger number of industrial people appear to believe that advance approval is neither necessary nor useful. And they fear that it would occasion interminable delays in some instances, especially in marginal cases.

Those who seek speedy and substantial progress, as well as public protection, argue that requirement of pretest and notification are all that is needed. Therefore this very considerable number opposes requirement of advance approval.

4. If advance official approval is not required by law, then a very simple measure amending the present Food, Drug and Cosmetic Act would suffice to give all the public protection needed, at a minimum cost and with minimum or negligible delay.

5. Those who take this latter position appear to back the type of bill drafted for National Canners Association. The presentation of this bill at the committee hearings has apparently developed a great deal of strong support for that proposed amendment. Apparently most of the chemical industry will support this position. Some divisions of the food industry, especially the Chicago group of food associations, appear opposed.

6. Some FDA officials strongly oppose anything that would restrict its authority for final and unrestricted prior decision in food-additive cases. They argue that this is their responsibility and, therefore, that they must also have full authority.

Probably a more important cause for this opinion is the disposition tending toward bureaucracy found occasionally in any regulatory body after a considerable period of official work.

7. One much-argued question is whether a Federal court review of FDA decisions shall merely take the form of appeals action in a circuit court, or whether some sort of injunctive or de novo (newly instituted) proceedings in the district court is necessary. The Judicial Conference opposes any de novo or lower court actions. This supports the FDA desire to keep all cases as appeals in the circuit court.

Here, many in industry object on the ground that even a minority support for an FDA finding would be considered sufficient to confirm the FDA findings, even when the predominance of evidence has opposed such administrative decision.

8. A simple law could solve this controversy as to court review by restricting administrative actions and appeals by either party to the present adequate procedures defined in the law. Undoubtedly, it would be much easier to get a simple bill passed in 1958, if proposals of new procedure were omitted.

But FDA opposes such policy. And a few of the food companies appear to support FDA, principally those who wish to have its prior approval on each new additive proposal (see point 2 above).

9. The question of carcinogens was brought several times into the additive-hearing discussion. Some of the more extreme critics—those opposing all additives on the ground that many of them might be carcinogens—were rather sharply refuted. Also, members of the committee seemed to be impressed with the imaginative, rather than realistic, status of such charges.

Apparently, an additive bill can be passed without any attention to the matter of cancer-forming elements—on the ground that the general additive pretesting automatically takes care of the carcinogen question.

10. Some members of the committee and the subcommittee seemed rather sharply critical of FDA relative to agency practices becoming "arbitrary and bureaucratic." In at least one case, the members were also critical of delays.

Most members of the committee recognized, by the end of the hearings, that if bureaucracy and delay prevailed to any considerable extent, there would follow both loss of progress in the use of additives and severe discouragement of research, especially by small companies.

11. Hinted at several times—but not clearly presented—was the fact that small companies suffered much more from restrictive rules regarding new additives than do large concerns.

Some members of the science panel pointed out that it often requires $50,000 to fully pretest a new additive, and that 2 years or more are generally needed. These facts clearly handicap companies of modest size, especially those with a limited number of products.

There, then, are the 11 uncertain points.

As for what's ahead, look for the subcommittee hearings to resume in 1958, perhaps in early February. FDA will then have the opporunity to present its case—which wasn't aired in 1957.

[Reprinted from Food Engineering, May 1957]

FE OPINION

Frank K. Lawler, Editor

FDA ADDITIVES BILL CONTAINS BOOBYTRAPS

There is special cause for concern about the chemicals-in-foods additive bill recently introduced by the Food and Drug Administration.

This bill might well receive more than normally favorable reception from Congressmen. It stems from a highly respected and ostensibly impartial Government agency. It was introduced with White House "clearance." And it includes a couple of apparent compromises to appease industry.

But contained in the proposed legislation are some provisions that are contrary to the best interests of both the industry and the public.

FDA's proposal would require industry to pretest and obtain approval of all new additives, the latter requirement being opposed by industry. Existing additives considered safe by experts would be exempt from such testing, a point of compromise on FDA's part but one still not satisfactory to industry.

Another concession by FDA is the provision that safe-use tolerances be established for ingredients that are toxic only in large amounts. The present law bars use in any quantity unless an additive is judged completely harmless.

GRANTS FDA DANGEROUS POWER

The bill would allow an FDA decision to be appealed to a Federal circuit court—but only on the question of the legality of the decision. Industry insists on the right to full-fledged trial on both legal and scientific issues. And it better keep on insisting, unless we want to risk one-man dictation as to what can and can't be introduced into foods in the interest of progress.

Federal control of advances in food quality and convenience is further strengthened by another provision. The new bill requires that utility be proved unless a new additive be "harmless." This may seem reasonably innocent on the surface. But utility would be decided by the Food and Drug Administrator. And suppose he be a zealot, with a mission to see that people eat foods as nature made them. Then he could, with legal impunity, bar worthwhile additives. That would impede progress in food manufacturing and discourage research on new ingredients.

This FDA bill should not be passed. Even though leaders in the food and chemical industries are weary of fighting for the right kind of chemical additives legislation, they certainly ought not to settle for such compromises as have been made to date by FDA. The bill gives too much power to FDA, and it would permit "legislation by regulation."

SIMPLE AMENDMENT THE ANSWER

Yet the delay in strengthening the pure food law already has been too long. With new additives being developed at an accelerating pace, there should be a requirement that industry report in advance its plans to introduce products containing new additives. This would automatically alert FDA, and it could take action if it does not consider a new additive safe.

So why not make a simple, noncontroversial amendment to the law to that effect? And do it right away?

That would protect the public, and without risk of FDA dictatorship or impediment to progress. FDA already has power to protect consumers against any food or ingredient considered dangerous to health.

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Add that one simple provision to the law soon. Then let the legislative protagonists squabble as long as they want. They could do so without risk to public health.

[Reprinted from Food Engineering, August 1957]

FE OPINION

Frank K. Lawler, editor

BACK NCA ADDITIVES BILL—IT'S SAFE, SANE

At long last, a safe and sane food additives bill has been proposed. It is H. R. 8390, written by Thomas Austern for National Canners Association, and introduced by Representative Harris on June 26.

Food and chemical manufacturers should come out of the fog of additive confusion and rally around this practical bill.

They will do well to push for its passage vigorously and concertedly before some other legislation is enacted that makes progress the price of additional consumer safety—that so strengthens FDA power as to pose the potential of one-man bureaucratic control of food manufacturing—that is so complex and ambiguously worded as to entangle all who become involved in a legalistic spiderweb.

PRETESTING PLUS NOTIFICATION

The new Harris bill constitutes the simple and constructive type of amendment to which we pointed in our May editorial criticizing FDA's additives bill for its booby traps. And it is written in clear, concise English that says what it means.

NCA's proposed amendment to the Federal Food, Drug and Cosmetic Act specifies that a new additive be pretested, with the evidence of safety being presented to the Secretary of the Health, Education, and Welfare Department, FDA's boss. Then the Secretary would, within 120 days, deliver his opinion (really FDA's) as to whether the additive has been adequately tested and is safe under conditions of its intended use.

If the evaluation be negative, the additive shall not be used without prior notice to the Secretary 90 days before the proposed first shipment. And this notice shall specify the identity of the additive and the food in which it is to be used, as well as the quantity, and designation and consignee.

That very effectively lays the cards face up on the table. Yet it does not give FDA all of the trumps.

At this point, if the Secretary believes he must act to protect public health, he may cause an appropriate injunction proceeding to be instituted with respect to such additive or the food containing it. And a temporary restraining order may be issued in accordance with Federal rules of civil procedure.

Another interesting provision of the bill is the exemption from penalties of anyone using a food additive if he establishes a guaranty signed by the person from whom he received the material. Such guaranty would be to the effect that as so used the additive or the food containing it is not adulterated or misbranded.

PROTECTS CONSUMERS, INDUSTRY

This simple bill effectively corrects the one potentially hazardous weakness of the present Federal food law. It prevents the use of a new additive without pretesting for safety and requires prior notice that alerts FDA.

If it is enacted, consumers are protected and interested parties can take their cool time to develop unemotional agreement on additional but less important refinements—if they so choose.

Not the least of benefits from its passage would be to take much of the wind out of the sails of politicians who make capital out of chemicals in foods.

P. S.: As this went to press, NCA's bill already was gaining influential backing. More power to it.

[Reprinted from Food Engineering, June 1957]

Confusion on Additives Hazard Calls for Basic Appraisal—By Cutting Through the Smoke of Controversy to Essential Fundamentals, a Safe and Sane Amendment to Food Law Could Be Enacted Quickly

Russell S. McBride,[1] editorial consultant, Food Engineering, Washington, D. C.

There is almost unbelievable confusion and controversy in respect to chemical-additives legislation.

Government officials and spokesmen of the food, chemical, cosmetic, plastic, and container industries are all involved. And the variation in opinion among industry groups themselves is as great as the differences between industry and government.

Both the public and the industry may suffer from this confusion. It is important to clearly determine what the consumer needs for protection against occasional hazards from either ignorant or careless enterprise. It is almost equally important to insure that new and worthwhile results of food research will not be stymied by needless restrictions.

POINTS OF AGREEMENT

Improper "additives" might be dangerous. Their use obviously should be eliminated or restricted within safe limits. This much is agreed to by all.

Industry willingly agrees that it must make the tests needed to insure that "improvements" are actually safe for the public.

Most people feel that Food and Drug Administration is the agency that must ultimately set up whatever controls are needed. How and under what rules are the disputed points involved in the confusion?

CAUSES OF CONTROVERSY

There are two causes for the controversy or fear which exists. First, there is demand for "absolute safety," which obviously is wholly impossible. Almost equally feared is the possibility that needless "bureaucratic" domination may become one consequence of new legislation.

Gradually developing is a realization that judgment of the safety of any additive must necessarily be based on the knowledge of many persons. And these persons must have the training and experience that give them clear understanding of all aspects of the problems involved.

Restrictions on novelty must not be so severe as to prevent real progress. To do that would discourage much research and deprive the consumers of many advances which they can reasonably demand.

Public safety and effective progress both can be had. Even now, cases of dangerous additive use seem actually unknown. Current warnings and worries are based only on what "might be serious," none proven.

It is not easy to define the proper limits that are needed. But the only sound appraisal will be that based on the unfettered judgment of experienced and independent persons, thoroughly acquainted with methods of pretesting and competent ot evaluate the results. (This does NOT mean appraisal by a National Research Council advisory committee.)

WHAT CAN CONGRESS DO?

Early legislative action is desirrable. But drastic or needlessly severe legislation will do more harm than good. Congress will not be taking final action in these matters in its first effort. However, it can well take long strides forward along the following simple lines:

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[1] Russell S. McBride has been an editorial consultant of Food Engineering since the founding of the magazine.

He also is a consulting chemical engineer serving numerous large food and chemical firms from Washington. So in this article he views the additives situation in the light of many years of intimate association with the problem.

The suggestions of the article are not offered by him, or by us, as a panacea for all present ills. But the article states the real problem, and it discusses an immediate palliative that might well be a satisfactory longtime remedy.—The Editors.

1. Industry can well be told by law that it must report to FDA in advance its plans for sale of foods containing new chemical additives. FDA can promptly serve the public only when adequately informed.
2. In support of each such proposal, industry can properly be asked to furnish the supporting evidence which in its judgment shows that the new material is safe under the proposed conditions of use.
3. The safety yardstick to measure hazard to the public should be clearly stated in the law. Congress should make it perfectly clear that the unfettered judgment of competent specialists, and all available facts, must be the basis for determining hazard to public health. Mere administrative judgment is not adequate.

CHANGES NOT NEEDED

Even as the food law now stands, the Commissioner can weigh evidence of safety and seek any further information believed necessary.

An adverse finding by him would, as a practical matter, effectively eliminate new materials if there be any real threat to public health. Several adequate disciplinary procedures already are available.

Without any new law, the Commissioner can reopen any case from time to time as need is found. He also can reappraise old practices which by new knowledge have been made suspect of hazard.

It is to be hoped that Congress will not either attempt now, or later find necessary, long and complicated definitions of procedures or restrictions. None of these can safely be substituted for sincere joint action of officials and industry.

From time to time, if need ever arises, Congress can take another look at the results of simple legislation and can add the new instructions as required.

CONGRESS WORRIED

The extravagant complaints and obvious conflict of interest in these matters is evident to Congress. It could hardly be otherwise. And Congress has started to do something about it.

A new subcommittee of the House Committee on Interstate and Foreign Commerce has been named to find out more about the ways in which FDA (among others) is administering the law.

One statement of the committee plan goes so far as to ask "whether the law and the statutory standards it contains have been and are being interpreted by rule, or internal procedures, to enlarge the area of regulation beyond that intended, and to administer it through procedures not intended by the Congress."

The special subcommittee intends to review past practice and redetermine the intent of Congress. This will permit a definite finding as to whether the per se doctrine is a valid and intended transfer of power from Congress to an administrative agency.

The Commissioner of Food and Drugs pointed out in a recent address "that we have never had a 'per se' rule against added poisons in the sense of an absolute prohibition."

But many past cases raise the question whether there has not been the practice of using the per se doctrine, with occasional very significant hardship on industry and disadvantage to the public. In fact, in one other public statement the Commissioner said that Congress had ordered absolute safety. That, of course, is nonsense.

FDA has been remarkably free from bigoted bureaucracy. But its dealing with scamps inevitably results in excessive suspicion as to motives or actions of even the most responsible persons.

In the third item mentioned above as a legislative need, a simple statement from Congress as to the intended safety yardstick actually will create greater safety. It would take advantage of informed scientific opinion and its full application in practice.

Let us hope that special congressional action will remove the temptation for excessive zeal. Then progress and safety may be fully protected against the hazards of mere controversy, which perhaps is the most dangerous of all.

RESOLUTION ADOPTED BY THE AMERICAN PUBLIC HEALTH ASSOCIATION, NOVEMBER 13, 1957, AT ITS ANNUAL MEETING IN CLEVELAND, OHIO

FEDERAL LEGISLATION ON FOOD ADDITIVES

Whereas the American Public Health Association in 1949 recommended to the Congress that it amend the existing Food, Drug, and Cosmetic Act to prevent the incorporation into foods of chemicals or other new ingredients before they have been reviewed and approved by the Food and Drug Administration; and

Whereas the Congress has enacted legislation directed to the control of residues of pesticide chemicals in food; and

Whereas possible legislation to require pretesting and approval, prior to their introduction in foods, of additives other than pesticide chemicals, is being considered or will be considered, by the Congress; and

Whereas it is in the interests of health of all consumers of foods that suitable legislation directed to this purpose be enacted; therefore be it

Resolved, That the American Public Health Association recommend to the Congress of the United States that legislation requiring the pretesting and approval, before use, of food additives not now covered by the Federal Food, Drug, and Cosmetic Act, or other Federal Acts, be enacted without delay.

FOOD AND NUTRITION SECTION, AMERICAN PUBLIC HEALTH ASSOCIATION

REPORT OF THE COMMITTEE ON CHEMICALS INTRODUCED IN FOODS

The enactment of Federal legislation to require an orderly procedure for the consideration and scientific evaluation of food additives, prior to their use in foods, was recommended by the American Public Health Association in 1949. The problems of food additives have been discussed by the Congress since 1950 and, though the calendar year of 1957 is drawing to a close, the objectives recommended by the association have not yet been fully attained. Considerable progress has been made, however. Since 1955 the Federal Food, Drug, and Cosmetic Act has provided for the control of residues of pesticide chemicals in foods, through a new section written into the act. The control of intentional additives, and all other additives other than pesticide chemicals, has not yet been written into the law. During the sessions of the 85th Congress, which were concluded late in the summer of 1957, hearings on a number of bills, each one intended by its sponsor to fill this legislative gap, were held by the House Committee on Interstate and Foreign Commerce. It is anticipated that during the 2d session of the 85th Congress these hearings will be resumed.

In general, the industries affected by the proposed legislation have expressed themselves as being in favor of provisions which would require the pretesting of proposed food additives to determine their safety under the conditions of use, and submission of the data to the Government agency administering the act before the food additives are used. Each bill contains this provision. Each bill also states in its preamble that it is intended for the protection of the public health. In other respects the bills differ very appreciably.

Before discussing some of the differences, it may be worth while to offer some comments on the question of whether or not legislation to control food additives is now necessary. There can be no doubt that there is today a much greater awareness of the potential dangers of incorporating additives to foods, when these additives are of unknown toxicity, than there was in 1949. The many discussions in scientific circles and in legislative committees during the last 8 years, first in the United States and more recently in many other countries, not to mention articles that have appeared in publications addressed to the general public, have served to make the problem well known, if not always well understood. The opinion has been expressed that this increasing awareness has served to minimize the need for legislation.

To some extent this statement is undoubtedly true. However, an incident came to light in late September 1957, which should not go unnoticed by persons interested in securing the greater assurance that appropriate legislation would provide. At the time mentioned there appeared in many newspapers a little item stating that the United States attorney had filed an injunction suit against the Continental Baking Co., which is probably the largest bread baking company in

the United States with annual sales of bread and cake which total about $300 million. Among the charges, which were based on an investigation by the Food and Drug Administration, was one that this company had used nitrated flour in the production of its Wonder and County Fair brands of so-called buttermilk breads.

What is nitrated flour? It is not an item to be found on the shelves of any grocery store. No homemaker has ever made use of such a product. Reputable millers do not produce nitrated flour.

The facts are that nitrated flour is a specialty product offered for sale to the baking industry. It was exposed several years ago as an example of a material that should not be used in foods without thorough testing because of its possible toxic properties. The material itself consists of flour that has been treated with diluted nitric acid, and subsequently dried. The process is patented. The nitrated flour is a fine powder with a brilliant orange color. When used in bakery products as a replacement for about 2 percent of the regular flour, it imparts to the crumb of the finished baked products a yellow color, which simulates the yellow color of egg yolks.

In the case involving the Continental Baking Co. the Government objected to the nitrated flour because it was not included in the list of permitted ingredients in the standards for enriched breads, which the products purported to be.

The United States District Court for the District of Columbia granted the preliminary injunction on October 3, 1957. The baking company stated that it had discontinued the use of nitrated flour in enriched bread in all its plants. This prompt action on the part of the company is commendable, because the injunction applies only to goods sold in interstate commerce, and it is not applicable to goods made and sold within a State. The prompt action of the regulatory authorities and the court is even more commendable. The present law did not permit action to be brought against the bakery products containing nitrated flour on the grounds that the ingredient had not been shown to be safe for use in foods, yet other provisions of the act were brought to bear, promptly and successfully.

It is obvious that the present Food, Drug, and Cosmetic Act is antiquated when it comes to the question of controlling additives which are purposely incorporated into foods.

In the discussions that have transpired concerning possible Federal legislation there has been, as has been stated, considerable difference in the details of the various bills to which consideration has been given. Resolution of these differences requires partly a legal background and partly a competence in the handling of scientific questions relating to public health. The committee desires to restrict its comments to opinions about scientific matters that come within its scope and capabilities.

First of all, it is gratifying to report that one of the comments in the statement of the committee's position regarding proposed legislation, published in the American Journal of Public Health in 1956, has been taken care of in some of the more recent bills. This comment was that the earlier bills did not appear to contain provisions for the adequate control of possible changes in foods brought about by radiation or radioactive material that might be used in newer methods of processing foods. It is important, in the committee's opinion, that new legislation which is adopted should contain language specifically directed to this purpose. As stated, some of the bills under consideration do now provide for this control.

A question that has been raised recently is whether the legislation should contain language which specifically bars the use of food additives that are capable of inducing cancer in experimental animals. The committee believes that it should not. We consider that specific reference to cancer in a new food additive section of the Food, Drug, and Cosmetic Act is not necessary and is, in fact, undesirable. We believe that the public health would be better protected without such a provision than with it.

This does not mean that the committee in any way minimizes the seriousness of cancer as a sign of toxicity in experimental animals. The appearance of any form of cancer in experimental animals must be given great weight in interpreting the results of feeding tests, just as is the appearance of cirrhosis of the liver or of histological changes in the kidneys which are indicative of nephritis, or the occurrence of many other pathological alterations of tissues and organs. The point is that any differences induced in experimental animals as a result of the test feeding of a proposed food additive must be evaluated and interpreted by scientists who are particularly skilled in this field. The proposal under discus-

sion would have the effect of taking a part of this responsibility out of the hands of scientists, where it belongs.

Perhaps a more important reason for not including specific reference to any disease in the law is the fact that there is at present no test that can be applied to a substance which will give absolute assurance that it will not exhibit toxic properties in human beings. The tests employed do give a high degree of probability, approaching certainty, that a substance is harmless under specific conditions of use in human foods.

Two other matters that have been discussed to a greater or lesser extent seem to call for some comment from the committee, if only because they have been discussed previously in the deliberations of the committee. One of these concerns what may be called the functional value requirement, and the other concerns what is sometimes referred to as the grandfather clause. The manner in which different views on these questions is resolved by the Congress may have significant bearings on public health.

Concerning the functional value requirement, the argument revolves around whether or not a proposed food additive, in addition to tests showing its safety for its intended use, must also be shown to possess some property, or confer some functional value, that is of benefit to consumers.

One view is that such a requirement is unnecessary, that other sections of the act would prohibit the use of an ingredient that would conceal inferiority or make a food seem more valuable than it is. The usefulness of some properties conferred by a food additive, it is held, is best left to the consumers to judge.

Another view is that evidence of functional value should be required only for food additives that exhibit some toxic properties, but are held to be safe for use under the conditions of use. It would be necessary to establish a tolerance for the permitted level of such additives.

The question could well be discussed further, particularly by those who are not in favor of the requirement that evidence of functional value of benefit to consumers be included in the law. Every food additive has an avowed purpose, else it could not be effectively sold. What is wrong with having a provision in the law that would give sponsors of a proposed food additive the opportunity to submit in their application, evidence to show what the additive will do and what it means, in the sponsor's opinion, to consumers of the food containing it? It would seem that reputable manufacturers would want to have the opportunity to submit evidence of the usefulness of their proposed food additives. The weight to be assigned to such evidence is a matter for judgment by the regulatory officials, to be determined largely by the nature of the other evidence submitted about the proposed additive, especially that regarding its its safety.

While the question of submitting evidence of functional value is probably one that requires further discussion, it would seem that there exists no valid reason for exempting from the requirements of testing those food additives that are currently in use. The objective of the legislation being sought is to protect the public health. The need for legislation has been discussed for at least 8 years. More time will elapse before any bill to control food additives is enacted and made fully effective. Surely in this time there will have been opportunity for prudent manufacturers to have obtained considerable experimental evidence about the toxicity or harmlessness of any additives now being used for which such evidence is insufficient or is lacking.

In concluding this report the committee once again is conscious of the difficulty of discussing the subject of chemicals introduced in foods without arousing in others some concern about the safety of our foods. There is no need for alarm. We are in no danger of mass poisoning from foods. It can be said that, with the passage of the section of the Federal act dealing with the control of residues of pesticide chemicals, our food supplies are better protected today than ever before in history. It is doubtless true that industry, on the whole, already is voluntarily examining newly proposed food additives to determine that they are safe for use, before they are used.

It is equally true that there can be no hardship in making mandatory a procedure which already is being followed. A new section of the Federal Food, Drug, and Cosmetic Act, to require adequate pretesting of food additives not covered by the act, or by other laws dealing with foods, is necessary in order to assure both manufacturers and the public that an orderly procedure is being

followed by everyone, and that competent scientific judgment is being brought to bear in the evaluation of evidence regarding the safety of all food additives. The time has come for the Congress to finish its deliberations and to enact the kind of legislation that is needed.

Respectfully submitted.

COMMITTEE ON CHEMICALS INTRODUCED IN FOODS,
FOOD AND NUTRITION SECTION, AMERICAN PUBLIC HEALTH ASSOCIATION,
FRANKLIN C. BING, Ph. D., *Chairman.*
FRED C. BLANCK, Ph. D.
OLAF MICKELSEN, Ph. D.
BERNARD L. OSER, Ph. D.
BERNARD E. PROCTOR, Ph. D.
GLENN G. SLOCUM, Ph. D.

STATEMENT OF MRS. J. A. BOORAS, WASHINGTON, D. C. TO HON. J. B. WILLIAMS, CHAIRMAN, HEALTH AND SCIENCE SUBCOMMITTEE OF HOUSE INTERSTATE AND FOREIGN COMMERCE COMMITTEE

Mr. Chairman, and members of the committee, health is one of our nations most precious possessions, as we live in a dynamic and changing world new problems face us daily, one of which is the safety of the food we eat. In years gone by many people raised much of their own food, small truck farms some time surrounded towns, in this way people could get a variety of foods in its original, primitive state from natural, organic soil. I remember as a child mother and I would drive out to the farm on Saturday to buy our fruits and vegetables.

Then as the population grew man was forced to confine himself to smaller areas of living, he then had to condition himself to the refinement, processing and storing of his foodstuffs, all of this done on a large scale.

In recent months I have read about chemical additives used in foods, as a housewife and because I have a responsibility to my family, I would like to have the assurance that I am buying the best available food for my family's health, as I understand it, these additives are the chemicals which are put in foods to improve color, texture, or flavor, or to lengthen the time that the food will stay fresh.

According to the Food and Drug Administration, there are about 150 chemicals used in foods today which have not been adequately tested for safety. The possibility of degenerative effect caused by taking small quantities of the chemicals in our bodies every day for years, because traces of these chemicals are absorbed and retained by foods so treated, so that there should be grave concern with what may happen to our younger generation, I feel sure the members of this committee share this same apprehension.

If a chemical does not serve a useful purpose it should not be used. But a safety tolerance should be established where it is necessary to use chemical additives and to spell out clearly the purpose so as to give every possible effective protection. Since the individual is powerless to protect himself against any threat from food to which chemicals have been added and since the use of chemicals in our modern food supply is a very large and complex subject the Federal Government must be empowered to inspect, test, approve, or to deny the use of the so-called additives if it endangers the health in any way. Because of my interest in this matter, I have listened to testimony given before the committee and read the other bills on chemical additives the one bill which meets specific protection against harmful use of chemical additives and is a marked improvement over the other bills is H. R. 7798, it also does not contain a grandfather's clause.

The carcinogen prohibition follows recommendations made by the International Union Against Cancer in Rome in August 1956.

In view of this chemical additives should be pretested specifically for carcinogenicity, and the only way to do this is through effective legislation.

I am deeply concerned with the entire food-additive problem, hearings and investigations have been going on for over 5 years seemingly nothing has occurred in the meantime to carry out and implement meaningful protection against dangerous chemical additives used on foods, as a homemaker I wish to have complete confidence in the safety of the foods which I buy, therefor I earnestly urge prompt passage of H. R. 7798 to safeguard the health of the people, the same safety requirements should be used for foods that now exist for new drugs and meats.

SUNKIST GROWERS,
Ontario, Calif., May 9, 1958.

Hon. JOHN BELL WILLIAMS,
Chairman, Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce, House Office Building, Washington, D. C.

GENTLEMEN: The pending food additive legislation studied by your committee is largely concerned with manufactured foods. Applications of pesticide chemicals to raw agricultural commodities are already controlled under the Miller amendment.

Most manufactured foods, however, at some stage of their perparation are derived from raw agricultural commodities. In the interest of maximum safety and minimum cost we have devised a "bridge" between the established raw agricultural commodity provisions and the new provisions for manufactured foods such as will comprise future legislation.

The proposal is briefly described in the attached single page. This, we are advised, will appear later this month in Food Technology. We are pleased to call it to your attention in advance of its publication.

Very truly yours,

WILLARD E. BAIER,
Manager, Research Department.

[To be published in May 1958 Food Technology]

A NEEDED ADDITIVE TO FOOD ADDITIVE LEGISLATION

(Willard E. Baier and Clarence W. Wilson, Sunkist Growers research department, Ontario, Calif.)

Proposed legislation is concerned mostly with new intentional food additives in prepared foods. The very proper goal is to provide for the same kind of pretesting that prevails now under the Miller amendment in the case of incidental additives in raw agricultural commodities.

There should be a way of avoiding the very expensive reconsideration of subtolerance levels of approved pesticide chemicals in raw agricultural commodities when these commodities are used in processed foods. Nothing is to be gained by compounding the provisions of existing and future legislation.

We propose, in defining new additives in legislation pertaining to processed foods, wording such as the following "The term new additive does not include a pesticide chemical in or on a raw agricultural commodity as defined in section 201 (q) of this act; nor such a pesticide chemical present in a processed food as the result, through good manufacturing practice, of being derived from a raw agricultural commodity which complies with section 408 of this act provided that its established tolerance when calculated to the basis of the nonaqueous matter content of the raw agricultural commodity is not exceeded in the processed food when similarly calculated; or a food additive or treatment in use prior to January 1, 1956, which presents no reasonable probability of injury to health; or any substance approved for use in food by or under this act."

Difficulties otherwise encountered in translating from raw to processed foods are avoided by referring both of them to the nonaqueous matter basis. The rationale of this concept was given in earlier articles.[1]

It is the confident belief of the authors that some such wording as above suggested has great potentiality. Improved safety will result. At the same time conserved effort easily equivalent to millions of dollars would accrue as compared with the alternative of reconsideration of each incidental additive in all foods into which it may be carried by the raw agricultural commodities. We see no reason for not using this simple device in proposed legislation.

(Whereupon, at 4:40 p. m., the subcommittee adjourned, subject to the call of the Chair.)

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[1] Baier, W. E., and Wilson, C. W., Food Technol. 5, 38–40 (1951), also Food, Drug, Cosmetic Law J. 9, 170–177 (1954).

[H. R. 10404, 85th Cong., 2d sess.]

A BILL To amend the Federal Food, Drug, and Cosmetic Act for the protection of the public health, by prohibiting new food additives which have not been adequately pretested to establish their safe use under the conditions of their intended use

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 201 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new paragraph:

"(s) The term 'new food additive' means any substance which, after January 1, 1958, is intended to be newly used for any purpose in the manufacture, packing, processing, preparation, or other fabrication of any food and thus to become a component of such food, but which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of food, as safe for use under the conditions of its intended use. The term does not include a pesticide chemical in or on a raw agricultural commodity, or any substance permitted in a food, by or under this Act. Each new food additive shall be deemed a food, for the purpose of this Act."

SEC. 2. Paragraph (j) of section 301 of the Federal Food, Drug, and Cosmetic Act is amended to read as follows:

"(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, or 704 concerning any method or process which as a trade secret is entitled to protection."

SEC. 3. Section 301 of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end thereof the following new paragraph:

"(o) A violation of section 400 (a) or (e)."

SEC. 4. Clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act is amended to read as follows:

"(2) (A) if it bears or contains any added poisonous or added deleterious substance, which is unsafe within the meaning of section 406, except a pesticide chemical in or on a raw agricultural commodity or a new food additive; or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a); or (C) if it is or if it bears or contains a new food additive which is unsafe for use under the conditions of its intended use;".

SEC. 5. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof the following new section:

"NEW FOOD ADDITIVES

"SEC. 409. (a) No person shall introduce or deliver for introduction into interstate commerce any new food additive or any food which bears or contains any new food additive unless (1) protesting data such additive have been fully submitted to the Secretary in accordance with this section, and (2) the Secretary has had an opportunity to evaluate said data, as provided by this section.

"(b) The pretesting data on a new food additive submitted to the Secretary shall include, in addition to any explanatory and supporting memorandums—

"(1) the name of and all available pertinent information about such additive, including its chemical identity and composition;

"(2) the conditions of the intended use of such additive;

"(3) all directions, recommendations, and suggestions for the use of such additive, including proposed labeling for such additive;

"(4) to the extent that it is necessary, to determine whether such additive is safe for use under the conditions of use, a description of—

"(A) the methods and controls used for the production of such additive, and

"(B) the methods available for determining the identity and quantity of such additive (including any known reduction products) in or on food;

"(5) a report of the pretesting investigations made to determine whether such additive is safe for use under the conditions of its intended use; and

"(6) any samples of such additive and its component articles, requested by the Secretary.

The Secretary shall hold such protesting data in confidence, except:

"(A) where such data has been submitted pursuant to section 409 (b) (1), (4) (B), and (5) and its disclosure either (i) has been authorized in writing by the person submitting it, in which event said data shall be published from time to time or otherwise made available by the Secretary to the public, or (ii) is required to protect the public health; or

"(B) where the disclosure of said data is required in an enforcement proceeding under this Act.

"(c) The Secretary shall promptly evaluate the pretesting data submitted by any person on a new food additive to determine whether in his opinion such additive is safe for use under the conditions of its intended use. The evaluation shall be completed within a period not exceeding one hundred and twenty days, unless it is extended by mutual agreement of the parties for a period not exceeding sixty days; and during this period such person may consult with the Secretary and submit additional pertinent data and memorandums.

"(d) When the evaluation has been completed the Secretary shall within ten days notify by registered mail the person submitting said protesting data on a new food additive, whether, in his opinion so reached, such additive is safe for use under the conditions of its intended use. If the opinion is favorable the Secretary nevertheless may thereafter modify or withdraw it by written notice to such person whenever new facts require this action to protect the public health.

"(e) No person who has thus received an opinion or a notice by the Secretary, pursuant to subsection (d), that a new food additive is unsafe for use under the conditions of its intended use shall thereafter introduce or deliver for introduction into interstate commerce such additive or a food bearing or containing it, without prior notice to the Secretary given by registered mail at least thirty days before the proposed shipment and disclosing its identity, quantity, and destination.

"(f) Whenever the Secretary then concludes that this action is necessary to protect the public health, he shall cause an appropriate injunction proceeding to be instituted under section 302 to restrain a violation of section 301 (a) with respect to such additive or a food bearing or containing it; and the final hearing in said proceeding shall be given precedence and otherwise expedited. In said proceeding a temporary restraining order may be issued in accordance with the Rules of Civil Procedure before the United States district courts promulgated under the Act of June 25, 1948 (ch. 646, 62 Stat. 961), as amended (28 U. S. C. 2072). For the purpose of determining whether such order shall issue, the relevant pretesting data submitted by the defendant under this section shall be taken as admissions by him. This subsection shall not be construed to preclude the institution of any other enforcement proceeding authorized by this Act, with respect to such additive or a food bearing or containing it.

"(g) No person shall be subject to the penalties of section 303 (a) for having received in interstate commerce and used in good faith a new food additive, if he establishes a guaranty, signed by and containing the name and address of the person residing in the United States from whom he received such additive, to the effect that the food bearing or containing such additive as so used is not adulterated or misbranded within the meaning of this Act.

"(h) The Secretary shall promulgate regulations to exempt from this section any new food additive and any food bearing or containing such additive intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of food."

SEC. 6. There are hereby authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purposes and administration of this Act.

SEC. 7. This Act shall take effect upon the date of its enactment.

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